

The critic's guide to bad vaping science

Version 1.0 – December 2016

Clive Bates

The informed critic's plain language guide to questioning the science of e-cigarette studies

Introduction	3
1 Toxic chemicals have been identified in e-cigarette vapor or e-liquids	3
1.1 Did they show potentially harmful exposure?.....	3
1.2 How risky compared to smoking?.....	4
1.3 How risky compared to other risks?	4
1.4 Were measurements made realistic human operating conditions?	4
1.5 Are inappropriate proxies being used for risk?	4
1.6 Are heroic but flawed analogies being used to suggest more risk than there is?	5
2 Adverse health effects from e-cigarettes are reported	5
2.1 Was vaping the cause?	5
2.2 Was the person suffering from adverse impacts a smoker before using e-cigarettes?	5
2.3 Is the study just observing the effect of nicotine on the body?	5
2.4 Is there evidence of actual harm or is it just a change in the body or brain?	6
2.5 Is it based on a cell culture study and are the limitations recognized?.....	6
2.6 Is it based on an animal study and are the limitations recognized?	6
3 Claims second-hand vapor is toxic and indoor vaping should be banned	7
3.1 Are exposures to second-hand vapor potentially harmful?	7
3.2 Is difference between risk and nuisance and its policy relevance understood?	7
3.3 Is the real question about who should decide: the law or the property owner?.....	7
4 Nicotine damages the adolescent brain	8
4.1 What is the specific nature of the harm to humans?	8
4.2 Where is the evidence for the damage in the human population of smokers?	8
4.3 How does this compare to damage from alcohol, cannabis or caffeine?	8
5 More children using e-cigarettes and gateway effects	8
5.1 Did they characterize use properly?	8
5.2 Could the rising use of e-cigarettes be a good thing?	9
5.3 High level of smoking associated with vaping?	9
5.4 Have they defined a gateway effect?	9
5.5 Are they assuming prior behavior caused the later behavior?.....	10

6	E-cigarettes keep people smoking and reduce quit rates.....	10
6.1	Has complexity of smoking and vapiin	10
6.2	Has the importance of product’s consumer appeal been recognized?	10
6.3	Was “dual use” described as problematic?	10
6.4	No benefit to cutting down?	11
6.5	Not enough randomized controlled trials (RCTs)?.....	11
7	Flavors and e-cigarette marketing aimed at children	11
7.1	Are they assuming that it is just obvious that childish names appeal to kids?	11
7.2	Why would adolescents try to emphasize their childishness?	12
7.3	Have preference for particular flavors been misrepresented as a cause of vaping?	12
7.4	Could it be a benefit that some flavors are attractive to adolescents?	12
7.5	Who is young?.....	12
7.6	Is an e-cig ad an anti-smoking ad?	12
8	Citing uncertainty and appeal to the 'precautionary approach'	12
8.1	Have they understood what is known?	12
8.2	Are they asking the impossible?	13
8.3	Do they realize that ‘precautionary approach can do harm to health?	13
9	Tobacco industry involvement implies inevitable harm	13
9.1	Is the malign influence of tobacco companies assumed or demonstrated?	13
9.2	Is there over-reliance on decades old statements, documents or behaviors?	14
9.3	Is there a proper understanding of how the nicotine market works?	14
9.4	Are the authors concerned about the right things?	14
10	Policy recommendations in a scientific paper.....	14
10.1	Do policy recommendations go beyond what their research justifies?	14
10.2	Have policy-making disciplines been followed?	15
10.3	Are the authors’ policy positions revealing biases?.....	15
10.4	Have unintended consequences been ignored?	15

Introduction

The volume and severity of untrustworthy fake news about e-cigarettes and vaping has now reached epidemic proportions. This can be down to naïve or cynical 'click-bait' journalism but just as often a result of scientists, journals, press officers or conference organizers overstating or misrepresenting their findings.

This paper takes ten of the common assertions made about e-cigarettes or vaping and suggest a line of skeptical questioning that should be adopted when such findings are presented. This is not to suggest such findings are always invalid, but that a degree of skepticism is necessary before accepting and repeating them.

This guide aims to provide an informed critic's plain language guide to questioning the science of e-cigarette and vaping studies. It is not a guide to the science itself.

1 Toxic chemicals have been identified in e-cigarette vapor or e-liquids

1.1 Did they show potentially harmful exposure?

Is there a little or a lot of the toxic agent? [It is important to distinguish between *hazard* and *risk*](#). Substances can be hazardous, but if the exposure to the body is low, then there may be no risk or negligible risk.

RISK = HAZARD x EXPOSURE

Put another way, '*the dose makes the poison*'. Almost all tap water contains a detectable amount of arsenic, for example, but so little that it poses no danger to anyone. Coffee contains at least 20 carcinogens, but coffee drinking is not linked to cancer. People are exposed to thousands of potentially toxic agents all the time, but suffer no harm because the body has defenses against most exposures up to a point. The amount of toxic chemical and the exposure it creates is what matters, and this needs to be shown to be a level that justifies concern. It is worth bearing in mind that even smoking does not appear to do lasting damage to life expectancy if a smoker quits before age 35 - for a smoker that started at age 15, that could mean 20 years of exposure to cigarette smoke without elevated mortality risk [[Doll & Peto et al Mortality in relation to smoking: 50 years' observations on male British doctors, BMJ, 2004](#)] [[Mortality graphic](#)].

1.2 How risky compared to smoking?

Many studies fail to put any e-cigarette vapor exposures in proper context and don't always include smoking as a comparator in measurements or in reporting. But e-cigarettes are designed to replace smoking and overwhelmingly used by smokers or ex-smokers. If a toxic chemical has been detected in e-cigarette vapor but at a concentration 1,000 times lower than in cigarette smoke, that is an advantage to nearly all users and the ratio of presence in vapor compared to smoke is a more relevant and valuable finding than merely the detection of a potentially harmful substance in vapor.

1.3 How risky compared to other risks?

Suppose you don't want a comparison with smoking, but want to compare vapor exposure to quitting completely or never smoking. We then should recognize that virtually nothing is entirely safe. The appropriate question is what degree of risk would represent a fair comparison from everyday life? We do not have zero appetite for risk, but tend to worry when risks are large and benefits small. If someone is saying that e-cigarettes are not zero-risk, have they made valid comparisons with occupational exposure limits, for example? What are the levels of residual contaminants allowed in approved licensed pharmaceuticals or food? The discussion of risk should be both *quantified* and *comparative*.

1.4 Were measurements made in realistic human operating conditions?

Some measurements have been made from vaping equipment used at temperatures that are never experienced by humans, yet these were used to project risks to human health. Many published findings have been based on overheating liquids and then measuring thermal degradation products like formaldehyde - but real vapers never experience these conditions because the taste is so awful. Overheating e-liquid, like burning toast, changes the chemistry. But just as people don't exist on a diet of blackened toast, vapers will almost never be exposed to overheated liquid.

1.5 Are inappropriate proxies being used for risk?

Calls to poison centers about e-cigarettes do not indicate a material risk of e-cigarette poisoning. Something new can easily create a high growth rate in calls but be trivial in absolute terms: for example, e-cigarette and e-liquid related calls to US poisons centers appeared to be growing rapidly from 2011-14, but these calls were in line with growth in media attention and a rapidly growing market, and even so accounted for about 0.2% of all calls in 2014, with calls related to medicines and household cleaning fluids greater by two orders of magnitude.

1.6 Are heroic but flawed analogies being used to suggest more risk than there is?

Have erroneous comparisons been used to suggest something is harmful in e-cigarette vapor because it has been found harmful elsewhere? For example, ultrafine particles in tobacco smoke or diesel fumes may be harmful because of their aggressive and complex chemistry. However, e-cigarette 'ultra-fine particles' (droplets of liquid aerosol) have completely different chemistry and physical characteristics, and there is no reason to suppose these particles pose a threat simply because of their size. However, the claim that ultrafine particles in e-cigarette vapor are harmful is often made without much justification.

2 Adverse health effects from e-cigarettes are reported

2.1 Was vaping the cause?

What grounds are there to believe that the vaping caused or contributed to the illness? A [small number of cases of lipoid pneumonia](#) have been [falsely attributed](#) to e-cigarette vapor for example, when e-cigarette use could not have been the cause. That's not to rule out health risks - nobody claims that e-cigarettes are *healthy* - but some care is needed before claiming a given health effect was caused by an e-cigarette.

2.2 Was the person suffering from adverse impacts a smoker before using e-cigarettes?

If illness develops in vaping patients, has their history of smoking or other risk factors for disease been adequately discussed as a possible cause? The risk of cancer and heart disease accumulated from smoking does not disappear at the point of switching to vaping or quitting completely - but no-one would say quitting smoking causes cancer. The CDC notoriously used a long-term smoker for anti-vaping advertising and implied blame for her lung ailment was attributable to her recent vaping.

2.3 Is the study just observing the effect of nicotine on the body?

There has been a succession of studies that observe changes to the circulatory system through various acute indicators (e.g. aortal stiffening, Flow Mediated Dilation). But these turn out to be physiological responses to stimulants like nicotine or caffeine or even exercise or music. Yet researchers have tried to argue because these effects are the same measured as in smokers (this no surprise if they are caused by nicotine) they will have the same cardiovascular impact as smoking. The data shows that nicotine when used independently of smoking, e.g. through long term use of NRT or snus use, is not a cause of a material cardiovascular disease risk. Acute bodily responses should not be assumed to be a reliable marker for chronic cardiovascular disease risk.

2.4 Is there evidence of actual harm or is it just a change in the body or brain?

Is the study reporting the fact of a physical change in the body or brain, rather than actual harm to health? Great care should be taken with neuroscience findings and claims for harm, brain damage or addiction based on imaging. The brain responds to stimuli, and this can be displayed in compelling MRI scan imagery. The appearance of stimuli *can* indicate harm but its presence doesn't prove it.

2.5 Is it based on a cell culture study and are the limitations recognized?

Was the study done on human tissue in the lab (*in vitro*)? These are known as cytotoxicity tests - they are useful for comparing toxicity of different substances under controlled conditions and can form part of a risk assessment. But the fact that cells are killed in these studies does not mean that a risk to human health is established, or that cells would be killed in the human body. It certainly does not prove that something causes cancer. Living cells in the body have an array of defenses that cell cultures do not have. Many *in vitro* studies detect cell damage from exposures (e.g. to nicotine), but no serious disease risk has been detected in human studies or epidemiology. A further problem with cell studies is creating a realistic proxy for human exposure. If the study has used exposures that are equivalent to 100 times higher than humans would experience for experimental reasons we cannot draw conclusions about human health. It is worth asking if the of limitations cell-culture studies acknowledged or ignored in presenting the findings? Further reading: [Cell studies on e-cigarettes: don't waste your time reading \(at least most of\) them.](#)

2.6 Is it based on an animal study and are the limitations recognized?

Great care should be taken in projecting results from animal studies to humans, especially if they are very dissimilar animals (e.g. rodents rather than primates). There are often huge differences between toxicological susceptibility between different animals - for example, the lethal dose of nicotine per kg of bodyweight that would kill 50 percent of an animal population (LD50) for nicotine varies dramatically between animal species. As with cell studies, the comparison between different things being tested is probably of greater value than speculative projection of a finding from animal to human. Beware of misinterpretations of certain types of animal study - some animals are bred for research purposes to have susceptibility to cancer. When interpreting animal studies, the following is essential reading: [Why journalists should stop publishing studies conducted with mice](#) (Laura and John Arnold Foundation).

3 Claims second-hand vapor is toxic and indoor vaping should be banned

3.1 Are exposures to second-hand vapor potentially harmful?

It is difficult to show that second-hand *tobacco smoke* is a source of material risk to bystanders in public places. The excess risk is small, the exposure hard to characterize and the science remains contested. Yet the exposures from the equivalent vaping will be *orders of magnitude lower*. Given that *active* use of vaping products creates very low exposures to users and given that there are no ‘sidestream’ emissions (these arise from the tip of the lit cigarette) where would the risk be coming from? We have seen more interest in second-hand or even third-hand nicotine exposures – these are so small as not to be pharmacologically relevant

3.2 Is difference between risk and nuisance and its policy relevance understood?

The primary justification for the intervention of the law is to protect workers or other bystanders from a material risk to health. Where the issues is of etiquette or nuisance, there is less justification for a legalistic approach, certainly in places where people can avoid going. For issues of nuisance and etiquette, it is more appropriate to let owners and operators to make decisions based on trade-offs

3.3 Is the real question about who should decide: the law or the property owner?

Have the authors jumped from their own preferences to an assumption that these should be codified into law? The alternative to a legal prohibition is not that people can vape everywhere, but that the owner of a property decides its vaping policy. On what basis would those calling for a ban justify banning vaping in the following circumstances?

- A bar wants to have a vape night every Thursday
- A bar wants to dedicate one room where vaping is permitted
- In a town with three bars, one decides it will cater for vapers, two decide not to allow vaping
- A bar manager decides on balance that his vaping customers prefer it and his other clientele are not that bothered – he’d do better allowing it
- A hotel wants to allow vaping in its rooms and in its bar, but not in its restaurant, spa, and lobby
- A care home wants to allow an indoor vaping area to encourage its smoking elderly residents to switch during the coming winter instead of going out in the cold
- A vape shop is trying to help people switch from smoking and wants to demo products
- A shelter for homeless people allows it to make its clients welcome

For all these decisions, the owner is best placed to judge and a powerful rationale is required to override these. If someone is calling for vaping to be prohibited by law, does their science provide this rationale?

4 Nicotine damages the adolescent brain

4.1 What is the specific nature of the harm to humans?

Though there are claims that nicotine causes harm to the adolescent brain, what is the nature of this harm and how is it manifest as an impairment in life? Does it make the user less intelligent, a slower learner, less adaptable, not so creative, emotionally stunted? What is the concrete form of the harm? Is this referring to changes that we otherwise refer to as ‘addiction’, and therefore nothing new?

4.2 Where is the evidence for the damage in the human population of smokers?

Given that people have been smoking for many decades at high smoking prevalence and often from an early age, where is the evidence of nicotine-based harm in the smoker or snus-user population? Is the existing smoker population suffering from some sort of damage to the brain?

4.3 How does this compare to damage from alcohol, cannabis or caffeine?

Some comparison is required to put this risk in context. What sort of harm is allegedly done, to how many users and with what short-term or lasting effect? Can this be illustrated with respect to damage to the brain that happened from other substance use?

5 More children using e-cigarettes and gateway effects

5.1 Did they characterize use properly?

When a high level of e-cigarette use is reported (“16% of teens are using e-cigarettes”), there are several questions to ask:

- Ignore ‘ever use’ – this is just a marker of experimentation in young people and does not give any meaningful information on risk
- If current use is quoted, how frequent is the use? In US 2014, 11.9% high school students used e-cigarettes in the last 30 days. But 45.4% of these had only used e-cigarettes on 1-2 days and only 9.7% (of the 11.9% = 1.1% of high school students) had used the products daily.
- Did smoking fall as vaping climbed? If the latter is substituting for the former, then it may be positive. In the US, teenage smoking rates fell rapidly as vaping increased.
- How much of the use was nicotine-based? The US data suggest that only 22% used nicotine last time they used an e-cigarette.

5.2 Could the rising use of e-cigarettes be a good thing?

Have the authors discussed whether e-cigarettes are displacing smoking, helping adolescents to quit smoking and, even in never-smokers, could it be an alternative to ever starting smoking? In other words, have the authors discounted the idea that the gateway is an 'exit' without justification? Does the population data show trends consistent with an exit or entry?

5.3 High level of smoking associated with vaping?

A study finds a pronounced *association* between two behaviors, A (e.g. vaping) and B (e.g. smoking) – for example the odds ratio. Four mechanisms are possible to explain what's happening:

1. A causes B: you've found a 'gateway effect'.
2. B causes A: this is what you would see if young smokers were keen to try vaping to quit or reduce their dependence on smoking. The e-cigarette use only happens because they were smoking. – this is known as 'reverse causation'.
3. C (a third factor or set of factors) causes *both* A and B: maybe the same things that incline adolescents to smoke also incline them to vape (e.g. parental smoking, rebellious nature), what is sometimes called 'shared liability'. More generally, this effect is known as 'confounding'.
4. Randomness – the sample doesn't represent the population.

Note that 2 and 3 are health-positive explanations for the behavior.

5.4 Have they defined a gateway effect?

Have the authors hinted at a gateway effect without explaining what they mean? Here's one possible articulation:

A harmful gateway from vaping to smoking arises if: someone who would not have developed a persistent smoking habit in a world without e-cigarettes, uses e-cigarettes and *as a result of this e-cigarette use* they develop a persistent smoking habit.

If this was happening it would be hard to detect because you need to know what would have happened in the absence of e-cigarettes - few researchers making this claim address this difficult issue satisfactorily.

5.5 Are they assuming prior behavior caused the later behavior?

Have the authors assumed that the *order* in which adolescents first try smoking and vaping matters in establishing a gateway effect? It doesn't matter at all. What matters is if vaping *causes* smoking to develop into a persistent habit, when it otherwise would not have done. If someone vapes before smoking, you would need to know what they would have done in a world without e-cigarettes: they may well have smoked anyway, which is likely if there is 'shared liability'.

6 E-cigarettes keep people smoking and reduce quit rates

6.1 Has vaping been wrongly conceptualized as though it is a medical intervention?

When a study claims to show reduced smoking cessation among vapers, the key questions are:

- **What behavior was examined?** Were the e-cigarette users observed trying to quit smoking? If not, then it is wrong to characterize the results as smoking cessation 'efficacy'.
- **Confounding?** Did those using e-cigarettes have the same characteristics as the overall sample? Or could they have been more highly dependent, less motivated etc? Had they already failed at quitting some other way?
- **Reverse causality?** If e-cigarette use is higher in smokers than in recent ex-smokers is that due to the smokers' preferences or the e-cigarettes?
- **Outcome measures?** Were the outcome measures limited to "quit smoking" but did not include "cut down substantially" as a benefit?

6.2 Has the importance of product's consumer appeal been recognized?

Are e-cigarettes reaching a section of the smoking population who would not otherwise try to quit, even if the quit rate is lower than in (say) Stop Smoking Clinics? A powerful medical aid that no-one wishes to use may be less effective at population level than one that is popular.

6.3 Was "dual use" described as problematic?

High levels of "dual use" (smoking and vaping continuing together) is not a problem unless the authors can show the dual users would otherwise have quit (which they no-one has done so far). It is inevitable that many people will use both, at least for a while - unless we had a 'magic bullet' that worked instantly and for everyone. Benefits still accrue to dual users: these include likely reduced toxic exposure and increased likelihood of eventual

quitting. Note that most people going through smoking cessation as dual users ([approx 93%](#)) - even if that means quitting completely, relapsing, trying again and repeating this cycle.

6.4 Did they claim there are no benefits to cutting down?

Studies that measure cutting down but without there being an alternative source of nicotine are unreliable proxies for the impact of cutting down with an alternative source of clean nicotine. Without alternative nicotine, smokers 'compensate' and smoke harder and consume more of the tobacco to maintain their nicotine dose. We do not have that many studies of people who have cut down with a replacement source of nicotine.

6.5 Not enough randomized controlled trials (RCTs)?

RCTs are often spoken of with reverence as the 'gold standard' of evidence - and in many situations they are. But they work best for simple interventions (like taking a prescription drug, using a certain teaching method, changing the wording on a tax demand) where one thing can be held constant and its impact measured. With vaping, there are multiple moving parts:

- What if more people want to use e-cigs? Hypothetically if 70% of smokers would be willing to try vaping and only 15% use a medical inhaler, an RCT that randomizes subjects equally to each will miss important information.
- What if, in real life, a user's purpose evolves? They start using it for convenience but it evolves to replacement of smoking and quitting?
- How to account for learning and improving technique - which may be due to many uncontrolled external factors?
- What if people evolve through different products as they gain experience, and the products themselves evolve?

It's possible to design RCTs to address some or all of these issues individually, but hard to do them all together. Observational surveys, cohort studies, case studies and testimonials all add value to the evidence base, while the limits of RCTs should be acknowledged.

7 Flavors and e-cigarette marketing aimed at children

7.1 Do they assume it is just obvious that childish names appeal to kids?

Have the authors just *assumed and asserted* that something with possibly childish characteristics (e.g. 'bubblegum' as a flavor name) will appeal to adolescents and that this has been done deliberately with that intention? Is there any data at all to support the claim?

7.2 Why would adolescents try to emphasize their childishness?

Have they considered that adolescents may prefer to emulate adult behaviors? (one study showed negligible interest in flavors in general, but to the extent there was interest the (non-significant) preference was for Tobacco Classic and Single Malt Scotch.

7.3 Have preference for particular flavors been misrepresented as a cause of vaping?

Once someone decides to vape, they need to choose a flavor (almost all vaping products are flavored with something) but it does not mean this preference caused them to vape to start with. How did the authors interpret the preferences for flavors and did they draw conclusions about flavors attracting adolescents to vaping from studies of?

7.4 Could it be a benefit that some flavors are attractive to adolescents?

Even if flavors did, in fact, encourage young people to vape, would this necessarily a bad thing? We know almost all vaping occurs among smokers or would-be smokers because there are common risk factors for both. If the appeal of vaping is to *young smokers*, is a flavor or flavor descriptor something that could persuade them to switch, and so a potential benefit?

7.5 Who is young?

Do the authors routinely refer to the more evocative term 'children', when the mean 'adolescents'? Are the authors misinterpreting marketing that is aimed at 25-30-year-old smokers, or aimed at adults who want a retro feel, irony or nostalgia? Many adults enjoy sweet 'candy' flavors and many like non-tobacco flavors to migrate away from the tobacco experience. Flavors may be important in denormalizing tobacco?

7.6 Is an e-cig ad an anti-smoking ad?

Is the practical effect of e-cigarette marketing a form of anti-smoking advertising, and potentially beneficial? It is advertising an alternative product to cigarettes, and an alternative lifestyle to smokers, but involving similar behaviors.

8 Citing uncertainty and appeal to the 'precautionary approach'

8.1 Have they understood what is known?

When researchers or activists say 'we don't know enough' do they know what is known and can they summarize that? Have they read the main evidence reviews? Or are they revealing

the are unwilling to engage with or accept what is known? Are there better experts to consult than people who claim not to know anything or that nothing is known?

8.2 Are they asking the impossible?

We obviously can't travel 50 years into the future and measure health effects of vaping several decades hence, and demands for that knowledge are disingenuous and impossible for *any* new product. We should use the information we do have to make best judgments of risks (e.g. data on chemistry of vapor, short term health impacts) and set these against the certain knowledge we have about the very pronounced risks of smoking. Isn't all policy-making a matter of making good judgements in the face of uncertainty - based on what is known, rather than paralysis by what is not known? On the other hand, is demanding certainty may be an activist tactic to raise impossible evidential hurdles? We still see activists claiming that it is unclear whether snus has had beneficial effect in Sweden, even though this is known beyond all reasonable doubt.

8.3 Do they realize that 'precautionary approach can do harm to health?

Don't trust anyone invoking the precautionary approach to justify onerous regulation of these products on the basis of incomplete evidence. That is because these products may have significant *health benefits* to smokers, and these benefits may be denied if the products are prohibited, access to them obstructed or undue caution applied on a 'precautionary basis'. This sort of precautionary action can be *reckless caution*. The Royal College of Physicians describes it as follows ([Nicotine without smoke: Section 12.10 page 187](#)):

A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.

9 Tobacco industry involvement implies inevitable harm

9.1 Is the malign influence of tobacco companies assumed or demonstrated?

Sometimes the tobacco industry involvement is evoked as a form of proof that whatever they are involved in must be bad for health and society. Likewise, the assumption that if the tobacco industry is opposed to it, then it must be good for health and society (the so-called

‘scream test’). However, the past is not always a reliable guide to the future and there is a danger that this approaches crudely and uncritically denies the possibility of shifts in the tobacco industry business model that may be beneficial for health and society, as well as for them. This is at least a *plausible possibility* for the move into vaping products. Have the authors assumed the involvement of the tobacco industry is necessarily and inevitably bad for health, without showing how harms would arise? Are they damning a product category just by association?

9.2 Is there over-reliance on decades old statements, documents or behaviors?

If the authors are drawing on historical statements or behaviors of the tobacco industry, how relevant are these now and is there anything to suggest they still apply? The historic behavior of these companies has been disgraceful and a reason for distrust and caution, but it cannot be assumed without evidence that the same behaviors persist through several decades, or on different issues.

9.3 Is there a proper understanding of how the nicotine market works?

When predatory or other malign behavior is alleged, do the authors base this on a realistic understanding of how markets, competition and consumer choice works, what drives tobacco company behavior and what incentives they have? For example, the tobacco companies compete in the e-cigarette market not to protect their cigarette business, but to gain or defend market share from other e-cigarette providers or to win market share from other cigarette vendors. Do the authors realize how consumer preferences and competition do not allow tobacco companies to dictate what consumers will buy and which technologies will succeed?

9.4 Are the authors concerned about the right things?

Have the authors understood how regulation benefits the tobacco industry, harms independent competitors, and defends incumbents against disruptive entrants? Have the authors reflected on whether their own policy preferences may protect the cigarette trade and gift the e-cigarette trade to tobacco companies?

10 Policy recommendations in a scientific paper

10.1 Do policy recommendations go beyond what their research justifies?

It is common to see policy recommendations included in the conclusions of a data paper that is narrow in scope. But policies require many different factors to be considered, usually

well beyond the scope of a single scientific paper. For example, economic or distributional consequences, unintended consequences and better ways to achieve the same result. Some policy issues also have a values basis to them and require value-judgements to be made by politicians – for example, respect for adult autonomy and degree of personal responsibility assumed. Have the authors made unqualified policy recommendations that are unsupported by their findings? It's a common and very bad trait among researchers and some journals to assume that publication of a data paper is a license to make policy recommendations, even though the policy was not the subject of the paper.

10.2 Have policy-making disciplines been followed?

Very few papers do enough work to justify a policy recommendation - scientific input is only one element of policy-making. In making policy recommendations have the authors drawn up an impact assessment and made an economic appraisal? Are distributional, ethical and legal considerations incorporated? Do they have a principled approach to the use of the law, restriction of liberty and for justifying public spending?

10.3 Are the authors' policy positions revealing biases?

Do the policy positions taken unconsciously reveal 'investigator bias'? By asserting particular policy prescriptions, they may be revealing biases or prior positions. Do these policy biases therefore cast doubt on the objectivity of the work? Is this a form of competing interest - usually unrecognized and non-financial - and should this be declared?

10.4 Have unintended consequences been ignored?

Have authors been rigorous at looking at unintended consequences. Authors often overlook unintended consequences that may arise from their favored policy ideas. Always ask: what could go wrong with this? For example:

- Banning e-cigarette advertising may 'hide' alternative to smoking or make this options seem less attractive
- Big bold warning on e-cigarettes might cause smokers to believe they are more dangerous than they are
- Banning flavors might reduce the appeal to certain adults and cause relapse to smoking
- Banning vaping in all public places might cause people not to switch, to relapse