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E-cigarette research needs to adopt open science practices to improve quality

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Open science practices provide important safeguards that serve to improve the replicability and integrity of findings. E-cigarette research is a highly contested domain that would benefit from greater adoption of these practices.

As scientists we are supposed to aspire to be seekers of truth, led to whatever conclusions the data take us. But in reality we are also human, and therefore subject to the same array of biases that apply to everyone, scientists and non-scientists alike (1). This includes a tendency to see patterns in our data that may not be there, the inclination to seek out evidence that confirms our preconceptions and a tendency to believe what we want to believe.

The scientific method protects against this to some extent, but concerns around the reproducibility of much published scientific research (2) have led to questions about whether the scientific method is being applied sufficiently rigorously. The prioritisation of novel "ground-breaking" findings, the emphasis on the data "telling a story", and the tendency for results that conform to the dominant narrative to be more readily published all conspire to undermine the robustness of published findings. Incentives to obtain a particular set of results, together with biases that encourage us to see what we're looking for, is a potentially damaging combination. Over time there has been a gradual move in biomedical journals to include conflict of interest (COI) statements, but these typically focus on financial COIs (and are themselves often imperfect and/or incomplete). There has been much less attention paid to the potential role of how cognitive and motivational factors shape the interpretation of evidence.

These issues are particularly acute in areas where there are strongly held beliefs and significant opportunities to produce impactful findings. One such area is e-cigarette research. The rapid increase in prevalence of a consumer product containing nicotine, that is purported to be much safer than smoking has brought to the fore some deeply held differences of opinion about tobacco harm reduction. The research and public health community has fractured, with different camps coalescing around different attitudes. The result is that we are seeing conclusions being drawn from e-cigarette research that appear to be based in many cases on pre-suppositions rather than a dispassionate analysis of the evidence and its context. We are also seeing researchers disputing or discounting conclusions that go against their view using criteria that they are not applying to conclusions that support their view.

For example, some researchers have claimed that correlational evidence convincingly demonstrates a causal association between youth e-cigarette use and subsequent smoking (3, 4), while others argue that these studies have not adequately dealt with unmeasured

confounding (5). Similarly, some researchers use correlational evidence to argue that e-cigarette use reduces smoking cessation rates (3, 6), while others argue that after taking into account selection bias and unmeasured confounding e-cigarette use actually *increases* population cessation rates (7, 8). Some researchers argue that RCT evidence supports the effectiveness of e-cigarettes for cessation, while others argue that RCTs showing positive effects have limited generalisability (see 9). The same evidence is interpreted very differently by different researchers.

Resolving disagreements on these issues cannot be achieved by simply accumulating more and more evidence with similar potential for bias and applying similar judgement processes to evaluating that evidence.

There is growing interest in approaches that may help mitigate research biases, and provide a level of quality control in our research workflows. 'Open research' practices, in particular, where some or all elements of a research workflow are made publicly-available, is one area where there has been a great deal of movement and innovation in recent years. This includes pre-registration of study protocols, sharing of study materials, posting of study data, and so on. This transparency can improve quality (for example, by requiring good data curation as well as increasing the level of checking that takes place before data are made public) (10). It can also help to protect against biases that can creep in once data have been seen (for example, by requiring clearly specified a priori hypothesis in pre-registered study protocols, so that additional analyses conducted after the data have been seen to be identified as post-hoc and exploratory). Journals have an important role to play here, for example by first having strong policies on protocol registration, data sharing and so on, and second by *enforcing* these policies robustly (11).

Importantly, open research practices can make it easier to fully scrutinise the evidence on which claims are based, introduce quality control checks, and protect against biases. In doing so, it can reduce the scope for inconsistent application of quality criteria and help to increase trust in findings that conform to these practices. Widespread adoption of open research practices, in particular pre-registration of study protocols and analysis plans, and ensuring data are FAIR (Findable, Accessible, Interoperable, and Reusable), would go some way to ensuring that the findings of e-cigarette research are robust and valid. This will require clear journal policies that are enforced. A number of initiatives currently being piloted may also help ensure we have a robust evidence base to inform policy – adversarial replications (12) and Registered Reports funding models (where a single review process provides applicants with funding with their work and in-principle acceptance of their results irrespective of the eventual outcome) (1). Given the critical importance of understanding the epidemiology of vaping, and its possible impacts on tobacco use, together with the strong feelings that have built up within the tobacco control and research community, adoption of such open science practices is an urgent priority.

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