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Title:

Applying recommended evidence standards to understand the impact of e-cigarettes on youth smoking and reporting of weak scientific evidence

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The authors have no financial or other relevant links to companies with an interest in the topic of this article.

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Concise Statement:

Evidence standards focusing on measurement of the outcome, measurement of the exposure and the study design could be helpful in assessing concerns over e-cigarettes acting as a gateway to smoking for young people. They might also help explain scientific uncertainty in cases where the best available evidence is weak.

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Commentary:

We applaud Villanti *et al* [1] for their review on the effectiveness of e-cigarettes for smoking cessation. We find their recommendations for rigorous evidence standards laudable and they apply these well to inform their weighing of the evidence. Villanti and colleagues address an important question, whether e-cigarettes help smokers quit or reduce smoking, a key reason many public health advocates welcome the expansion of the e-cigarette market [2]. In contrast, others have raised concerns about the potential of e-cigarettes to re-normalise smoking behaviour or provide a gateway into tobacco smoking for younger generations [3, 4], although so far there is limited evidence to support this [5]. We discuss how similar rigorous evidence standards might be applied to answer such concerns, and suggest lessons for media reporting of weak evidence.

If our question is whether e-cigarettes could lead to increased uptake of tobacco smoking among youth, then we might follow Villanti *et al* [1] in developing evidence standards by thinking about measurement of the outcome, of the exposure, and the extent to which the study design allows causal inference.

Criterion 1 from Villanti *et al* [1] relates to the measurement of the outcome. Studies of impacts on youth uptake of smoking should focus on a relevant outcome, for example, by measuring rates of uptake, or the stages of this process such as initiation, escalation to daily smoking, or early quitting [6]. Studies utilising such outcome measures will be of greater value than those merely focused on prevalence of tobacco smoking.

Villanti *et al*'s [1] criteria 2, 5 and 6 relate to adequately measuring the exposure. Criterion 2 is exemplary in considering the mechanism of action (that cessation studies are only interested in e-cigarette use for cessation). Criteria 5 and 6 might be relevant if considering adolescents' own use of e-cigarettes as a gateway to tobacco smoking, but adolescents' own use is not the only exposure mechanism relevant to this question. Concerns about e-cigarettes re-normalising smoking behaviour, mean that exposure to others' use of e-cigarettes is also relevant. This might be proxied by population prevalence, but better evidence would come from more direct measurement (e.g. a parent, sibling or peer's use of e-cigarettes).

Criteria 3 and 4 in Villanti *et al*'s paper [1] relate to whether the study design supports causal inference. Temporal precedence of the exposure before the outcome (criterion 4) could be considered necessary but not sufficient to demonstrate causality, as observational associations between exposure to e-cigarettes and youth take-up of smoking may still be confounded by prior common causes (e.g. personality, socioeconomic position etc.), even if smoking occurs after e-cigarette exposure. Criterion 3 will be more critical as we would be unlikely to see ethical RCTs of e-cigarette impacts on youth smoking uptake. Epidemiological evidence should be carefully controlled for potential confounders, ideally going beyond simple demographics, but even so confounding influences may remain. A more robust avenue may be use of natural experiments, where some event, policy change etc. results in a rapid change in exposure to e-cigarettes that is not associated with other confounding factors [7].

The swift expansion of e-cigarette usage means it will take time for studies meeting such rigorous criteria to be conducted. In the interim, weak evidence may be the best evidence available. In such a controversial field, with a high degree of media interest [8], and given media influences on public understandings [9], researchers need to delicately balance what we know against what we don't yet know. For example, Villanti *et al*'s conclusion that "e-

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cigarettes can help with smoking cessation or reduction” [1] needs to be tempered against their conclusion that only a small proportion of studies (4 of the 91 reviewed) met their quality standards to support such a statement. Scientific uncertainty needs to be expressed clearly, but can also be used on both sides of a debate, for example, uncertainty over the health risks associated with e-cigarette use has been used to argue both for and against regulation [8]. Thus, extra care is needed to neither over-state nor under-sell available evidence. Evidence standards could be useful tools for explaining what weaknesses exist in available evidence, and how this affects our certainty over the interpretation of the findings.

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