Jury out on whether heated tobacco products are less harmful for health

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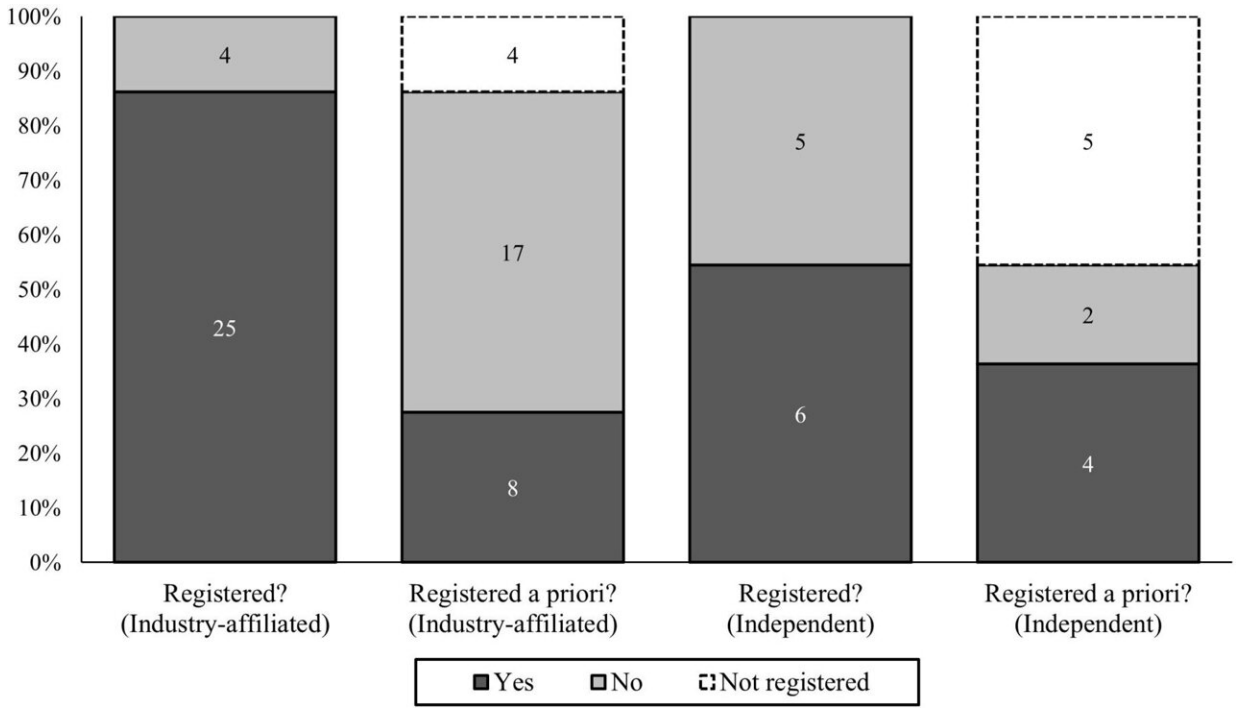

Number of trials that were registered on a clinical trial registry ('Registered?') and whether they were registered prior to enrolment of the first participant ('Registered a priori?'). Size of bar indicates percentage of trials. Number within bar indicates number of trials. Credit: *Tobacco Control* (2022). DOI: 10.1136/tc-2022-057522

The quality of evidence available about heated tobacco products is substandard and policymakers should be wary of claims made about

their role in harm reduction, say the authors of a new study.

Heated tobacco products (HTPs) are designed to heat tobacco to low temperatures. This produces an inhalable nicotine aerosol which purportedly reduces the amount of toxins released and therefore the health risk to consumers, compared to cigarettes.

These products are different to e-cigarettes. Whilst e-cigarettes heat liquids or salts (which typically contain nicotine), HTPs heat tobacco leaf. Any device that contains tobacco leaf cannot be classified as an e-cigarette.

The 'harm reduction' claim—that HTPs are safer—has helped to grow their popularity worldwide. In 2018, PMI's IQOS (the global market leader) was available in around 30 countries; by 2021, it was marketed in 71 countries, including the UK and US.

Yet, a new study from researchers at the University of Bath published this week in the *BMJ's Tobacco Control* argues that the evidence underpinning these claims is largely unrepresentative of real-world use and at high-risk of bias.

Its analysis of 40 publicly available clinical trials for HTPs found that 29 were tobacco industry affiliated or funded. Most of the available clinical trials were also judged 'at high risk of bias' given their methodology and choice of study design.

The most common reason for studies being at high risk of bias was performance bias, whereby the interventions allocated were known to participants and those conducting tests. There was also failure to report all results data for all trial measurements, known as selective reporting bias.

The authors argue that presence of these biases compromises the validity of trials and can lead to overestimation of the effects of HTPs. They also identified further limitations within trials, including short durations, restrictive conditions unreflective of real-world circumstances, and a lack of relevant comparators, like e-cigarettes.

These all raise concerns over how representative existing clinical trials are of HTP use in the real world.

As such, the team at Bath's Tobacco Control Research Group say much more detailed, independent research is now needed to assess the true short- and long-term health effects of HTPs.

In the meantime, they argue that consumers should be wary of harm reduction claims and that policymakers and regulators should carefully consider the usefulness of these trials when making decisions surrounding HTPs.

Lead researcher, Sophie Braznell from Bath's Department for Health explained, "Over recent years we have seen great expansion in the heated tobacco market in the UK and around the world. This growth has been predicated on a marketing claim that these products are better for health, in comparison with traditional cigarettes."

"Our analysis suggests that the picture is far less clear-cut. The clinical trials available, which are used by the tobacco industry to substantiate these claims, were often substandard in terms of how studies were conducted and reported, and most were industry-affiliated in some way."

"As more consumers move away from cigarettes towards these new generation products, we need much better evidence to assess their health impacts now and into the future. In the meantime, the jury is very much still out on their benefits."

Co-author on the paper, Dr. Gemma Taylor from the Addiction & Mental Health Group and Deparmtent of Psychology at the University of Bath added, "These findings in relation to clinical trials for heated tobacco products are significant and we need to be wary of health claims made."

"At the same time though, it is important to note the clear distinction between 'heated tobacco products' and 'e-cigarettes'. Consumers and health policymakers must not equate the potential benefits of e-cigarettes in helping people to quit smoking with heated tobacco products."

More information: Sophie Braznell et al, Critical appraisal of interventional clinical trials assessing heated tobacco products: a systematic review, *Tobacco Control* (2022). DOI: 10.1136/tc-2022-057522

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