Electronic cigarettes for smoking cessation

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In *The Lancet*, Christopher Bullen and colleagues[1] report the results of a study that is likely to have an important effect on the discussion of the role of electronic cigarettes (e-cigarettes) in tobacco control. Bullen and colleagues randomised 657 adult smokers wanting to quit to 16 mg nicotine e-cigarettes (as needed), 21 mg nicotine patches (one per day), or placebo e-cigarettes (no nicotine, as needed) in a 4:4:1 ratio. Participants, who all lived in Auckland, New Zealand, could access the national Quitline (a telephone counselling service), but received no additional support. At 6 months, 21 of 289 (7·3%) participants in the nicotine e-cigarettes group had achieved biochemically verified abstinence, compared with 17 of 295 (5·8%) participants in the patches group, and three of 73 participants (4·1%) in the placebo e-cigarettes group (risk difference for nicotine e-cigarette *vs* patches 1·51 [95% CI −2·49 to 5·51]; for nicotine e-cigarette *vs* placebo e-cigarette 3·16 [−2·29 to 8·61]). 57% of participants in the nicotine e-cigarette group had reduced tobacco cigarette consumption by at least half at 6 months, compared with 41% of those in the patches group (p=0·0002) and e-cigarettes received higher user endorsement than patches. Adverse events were generally not serious, and were much the same across groups.

The study provides valuable data, but it has limitations. The investigators measured sustained validated abstinence, which is the right outcome for this type of trial, but its power calculations used much higher unvalidated 7-day abstinence rates. This meant that the study was underpowered and so presents only tentative findings. There is also the issue of testing a new treatment in a suboptimum setting. The standard approach to assessment of new treatments includes careful supervision and monitoring of treatment adherence to increase the likelihood that treatments are used as intended. In this case, little effort was made to ensure that participants were using the e-cigarettes. The same was, of course, true for patch use, but more would have been learned from a comparison of two treatments used to their full potential.

Despite these caveats, which the investigators acknowledge, this was a pioneering study and it did generate new and useful information. The key message is that in the context of minimum support, e-cigarettes are at least as effective as nicotine patches. E-cigarettes are also more attractive than patches to many smokers, and can be accessed in most countries without the restrictions around medicines that apply to nicotine replacement therapy or the costly involvement of health professionals. These advantages suggest that e-cigarettes have the potential to increase rates of smoking cessation and reduce costs to quitters and to health services.

The main untapped potential of e-cigarettes, however, might not be in treatment of the minority of smokers seeking help with quitting, but rather as a safer consumer product for use by smokers in general. Such use could ultimately lead to the disappearance of combustible tobacco products and to the end of the epidemic of smoking-related disease and death. To rival cigarettes in providing what smokers want, e-cigarettes need to develop further, but under the pressure of market competition, they are currently undergoing a fast evolution and are likely to keep improving.

Concerns have been expressed that rather than reducing or even replacing traditional smoking, e-cigarettes could increase smoking rates by attracting new recruits and reducing quit attempts. This situation is usually implied by the phrase "renormalising smoking". Such an outcome seems counter-intuitive and contradicted by the present study[1] and by other data currently available,[2-4] but it is theoretically possible. There is an obvious source of evidence as to whether use of e-cigarettes leads to an increase or reduction in tobacco smoking: the trajectories of sales of e-cigarettes and tobacco cigarettes. If growing sales of e-cigarettes coincide with increased sales of tobacco cigarettes, tobacco control activists arguing for restriction of e-cigarette availability would be vindicated. If traditional cigarette sales decline as e-cigarette sales increase, it would suggest that e-cigarettes are normalising non-smoking and that it is in the interest of public health to promote and support their development rather than try to restrict it. The European Union and UK are currently proposing to regulate e-cigarettes as medicinal devices, while leaving cigarettes available on general sale.[5,6] If this regulation goes ahead, tobacco cigarettes will retain their market monopoly and we will never learn whether e-cigarettes would replace traditional cigarettes if allowed to continue evolving and competing with smoked tobacco on even terms.

There hardly exists a commentary that would not recommend more research, and this one is no exception. More data are needed on the efficacy of e-cigarettes in smoking cessation and in harm reduction (when used under different conditions and compared with different comparators); on their long-term safety, both in comparison with cigarettes (whereby e-cigarettes can be expected to be orders of magnitude safer[7]) and in absolute terms (whereby some health risks might yet emerge[8]); and most importantly, on the effect that increasing e-cigarette sales are having on sales of tobacco cigarettes. In terms of practical implications of the results of the study by Bullen and colleagues, stop-smoking services which distribute nicotine replacement therapy with minimum support now have a cheaper alternative to consider, and health professionals will now hopefully feel easier about recommending e-cigarettes to smokers, or at least condoning their use.

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I have received research funding from, and provided consultancy to, manufacturers of smoking cessation medication. I have no connections with any manufacturers of electronic cigarettes.

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