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Nicotine patches with e-cigarettes for smoking cessation: Twitter discussion from a respirology journal club

Authors' reply

The *Lancet Respiratory Medicine* published a letter by Nermin Diab and colleagues (2020)¹ about our three-arm trial investigating the effectiveness and safety of nicotine patches combined with e-cigarettes (with and without nicotine) for smoking cessation.² We wish to address two points made by the authors of the letter.

First, they say, "...it would seem preferable to establish the efficacy of nicotine e-cigarettes before doing a pragmatic trial".¹ We would suggest that both efficacy and effectiveness trials are important, but they serve very different purposes and provide very different information. Both designs have pros and cons—the choice of design relates to the research question of interest, is context specific, and one does not need to occur before the other. Efficacy trials are highly controlled (both in patient population and conduct) and their findings are therefore not translatable to the real world. In comparison, trials on the effectiveness of e-cigarettes have the most relevance for decision making by health-care policy makers and health-care providers. Such trials tend to have a usual care comparator, but can be expensive to do as they often require a large sample size and long-term follow-up. It is important when reading effectiveness trials to consider the context of the trial (ie, the country in which it was done, and the country's policy environment). In New Zealand, a country with a smoke-free 2025 goal and the urgent need for policy relevant information about the

effect of e-cigarettes on quitting, our effectiveness trial design was the most appropriate design to answer the policy-based research question.

When our trial findings are considered in their entirety, one can see that they are consistent across different time points, measures of cessation, and with most of the sensitivity analyses supporting the conclusions. We acknowledge the authors' comments about the desirability for more frequent verification of smoking status. However, New Zealand is a small country (of approximately 5 million people) with little public research funding available. It was not feasible or affordable to do more extensive follow-up of our trial participants, as they were geographically dispersed throughout the entire country and we had only around US\$400 000 to run a three-year trial. Our chosen measurements of abstinence are those recommended by the Society for Research on Nicotine and Tobacco for pragmatic trials.³ In New Zealand, we do not have access to large pools of research funding, so must maximise our use of every dollar. Efficacy trials of little relevance to the population using e-cigarettes are a poor use of our time and money.

Second, they say, "...the findings are not readily generalisable given the multitude of e-cigarette brands and delivery systems available worldwide and probably different amounts of nicotine content from that used in the trial."¹ We agree, but no efficacy or effectiveness trial of e-cigarettes will ever be fully generalisable. Nor is it possible to design a trial where every type of e-cigarette ever designed (and nicotine concentration) can be evaluated. However, there are other pathways to inference than those of drug evaluation. In this case we have created generalisable evidence as proof of principle that nicotine-containing

e-cigarettes combined with nicotine patches will increase quit rates. We tested the type of e-cigarette (and nicotine concentration) that was the most popular amongst naive e-cigarette users in New Zealand at the time the trial was done. Newer devices are known to deliver nicotine more efficiently and effectively, so one can assume quit rates would be higher.

NW, CB, MV, GL, ML, and VP report grants from the Health Research Council of New Zealand, during the conduct of the study. NW, CB, MV, and VP report grants from Pfizer, outside of the submitted work. GL chairs the organisation End Smoking New Zealand, which advocates for harm reduction approaches to tobacco control. E-cigarettes were purchased from a New Zealand e-cigarette online retailer (NZVAPOR, <https://www.nzvapor.com/>), e-liquid was purchased from Nicopharm, Australia (<https://www.nicopharm.com.au/>), and nicotine patches were supplied by the New Zealand Government via their contract with Novartis (Sydney, Australia). NZVAPOR also provided, at no cost to participants, online and phone support regarding use of the e-cigarettes. Neither NZVAPOR nor Nicopharm have links with the tobacco industry. None of the above parties had any role in the design, conduct, analysis, or interpretation of the trial findings, or writing of this publication.

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- 1 Diab N, Stanbrook MB, Khan MH, Anand A. Nicotine patches with e-cigarettes for smoking cessation: Twitter discussion from a respirology journal club. *Lancet Respir Med* 2020; **8**: e7.
- 2 Walker N, Parag V, Verbiest M, Laking G, Laugesen M, Bullen C. Nicotine patches used in combination with e-cigarettes (with and without nicotine) for smoking cessation: a pragmatic, randomised trial. *Lancet Respir Med* 2020; **8**: 54–64.
- 3 Benowitz NL, Bernert JT, Foulds J, et al. Biochemical verification of tobacco use and abstinence: 2019 update. *Nicotine Tob Res* 2019; published online Oct 1. DOI:org/10.1093/ntr/ntz132.