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What should physicians say about electronic cigarettes?

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If you haven't already been asked about them, you will be. So, you need to have an answer. Maybe this will help.

Electronic cigarettes (or "e-cigarettes") were reportedly invented by a Chinese pharmacist who wanted to find a safer way for smokers to inhale nicotine, after his father, a cigarette smoker, died from lung cancer. The basic e-cigarette design is a lithium battery attached to a heating element that vaporizes a solution of either propylene glycol or vegetable glycerin and liquid nicotine. Vaporization allows for inhalation, referred to as "vaping" as opposed to smoking.

There should be little debate about whether smokers should have access to these products. They do right now, and the products are unlikely to be banned in the near future, although age restriction is a moving target. Debating access seems nonproductive and a distraction from the real discussion.

The real discussion should focus on whether public health and medical health professionals should be recommending them for treatment.

Two important questions need to be answered:

• First, are they safe? Answer: We have no long-term safety data on the impact of repeated inhalation of propylene glycol or vegetable glycerin on lung tissue. Some short-term data suggest that e-cigarettes may cause airway irritation.

• Second, are they effective for increasing smoking cessation?

To help answer the second question, Dr. Christopher Bullen and his colleagues published a randomized, controlled clinical trial evaluating the comparative efficacy of 16-mg nicotine e-cigarettes, nicotine patches (21-mg patch, one daily), or placebo e-cigarettes (no nicotine) (Lancet 2013 Sept. 9 [doi:10.1016/S0140-6736(13)61842-5]). Potential participants were eligible for enrollment if they were at least 18 years of age, had smoked at least 10 cigarettes per day, and wanted to stop smoking. All participants were referred to the telephone quit line for behavioral counseling. Participants were treated for 13 weeks.

At 6 months, smoking abstinence was 7.3% with nicotine e-cigarettes, 5.8% with the nicotine patches, and 4.1% with placebo e-cigarettes. The risk difference for nicotine e-cigarettes vs. patches was 1.51; for nicotine e-cigarettes vs. placebo e-cigarettes, it was 3.16. Neither difference was statistically significant. Interestingly,

e-cigarettes were associated with greater reductions in cigarette smoking, compared with nicotine patches. (None of the study's authors reported having any relevant conflicts of interest.)

So, back to the second point. E-cigarettes are clearly not superior to nicotine patches, but this study may have been underpowered because absolute abstinence rates were low.

Currently, e-cigarette manufacturers are spending resources manufacturing and marketing rather than assisting in the creation of reliable scientific data or the creation of an international research agenda on these products.

One day, an e-cigarette device may be part of a clinical treatment program for tobacco dependence. But until that day, clinicians need to be justifiably circumspect in recommending e-cigarettes for use among cigarette smokers.

Why? Because:

• They are not clearly superior to Food and Drug Administration–approved medications for smoking cessation.

• They are not FDA approved for treatment.

• Short-term safety data suggest they may cause airway irritation.

• Long-term safety data do not exist.

• Smoking reduction is arguably not a relevant clinical outcome, because a significant increase in tobacco-related risk occurs at low levels of exposure.

For clinicians, treatment recommendations are married to the responsibility for unintended consequences. What are those unintended consequences with electronic cigarettes? We need more data.

Dr. Ebbert is professor of medicine and a primary care clinician at the Mayo Clinic in Rochester, Minn. Dr. Ebbert has received consulting fees from GlaxoSmithKline, manufacturer of nicotine replacement products, and research support from Pfizer, manufacturer of varenicline. The opinions expressed are those of the author.
