E-CIGARETTES

FACTS & RECOMMENDATIONS

RECOMMENDATIONS

- It is recommended that e-cigarettes are not added to hospital formularies. E-Cigarettes are neither an FDA-approved treatment nor a regulated device.
    - The FDA, CDC, World Health Organization, U.S. Veterans Administration, American Cancer Society, American Lung Association, American Heart Association, Campaign for Tobacco-Free Kids, Action on Smoking and Health, American Legacy Foundation, American Academy of Pediatrics, and the Association for the Treatment of Tobacco Use and Dependence have all issued statements expressing concern about the safety of these products and/or recommending that e-cigarettes not be used for tobacco cessation.
    - On April 16, 2013, five U.S. Senators called on the FDA to issue "deeming regulations" asserting regulatory authority over tobacco products, such as electronic cigarettes, and to restrict the sale, distribution and marketing of e-cigarettes and other nicotine products to children and young adults.
- It is recommended that healthcare providers share concerns about the lack of information regarding the safety of these consumer products and to inform their patients (and staff) about the difference between these products and FDA-approved Nicotine Replacement Therapy (skin patches, gum, lozenges, oral inhalers, and nasal sprays) and bupropion SR and varenicline. Providers should also provide information about the efficacy of behavioral counseling and FDA-approved medications as first-line treatments.
- It is recommended that healthcare providers share information about the potentially life threatening consequences of intentional or non-intentional exposure to nicotine in the nicotine refill bottles.
- It is recommended that e-cigarettes should be included in smoke-free and tobacco-free policies for healthcare agencies.

WHAT IS AN E-CIGARETTE?

The "e-cigarette" (electronic cigarette) is a product designed to mimic the effects of smoking without burning tobacco like a traditional cigarette. The e-cigarette is a battery-powered device that provides inhaled doses of nicotine by delivering a vaporized propylene glycol/nicotine solution. In addition to nicotine delivery, this vapor also provides a flavor and physical sensation similar to that of inhaled tobacco smoke. Because there is no combustion of tobacco, e-cigarettes are marketed as being a safer alternative to cigarettes and as a product allowing people to 'smoke' in places where there are smoke-free indoor air policies or laws. The e-cigarette has been proposed by its manufacturers as a safe and effective way to help people stop smoking.

China began creating e-cigarettes in 2004 and produces most e-cigarettes today. E-cigarettes began to be sold in the U.S. in 2007. Currently, there are over 100 brands of e-cigarettes, and 3.5 million devices were sold in 2012. While e-cigarettes were not developed by the major tobacco companies, these companies are starting to buy e-cigarette brands. In April 2012, Blu E-cigs was purchased by Lorillard Corporation for $135 million.

PREVALENCE OF USE

Based on a 2012 U.S. survey (N=10,041) about 8.1% of individuals had tried e-cigarettes and 1.4% were current users. Among current smokers, 32.2% had tried e-cigarettes and 6.3% were current users (Zhu et al., 2013). Another study found that more than twice as many adult smokers used e-cigarettes in 2011 as in 2010 (King, Alam, Promoff, Arrazola, & Dube, 2013), with approximately 21% of current smokers using electronic cigarettes at least once in 2011.

There is some evidence that e-cigarettes do decrease tobacco use. For example, one uncontrolled and industry-sponsored study that was not reviewed by an ethical board found that 32.5 % of smokers not interested in quitting smoking reduced their cigarette consumption by 50% at week-24,, and an 80% reduction was seen in 12.5% participants (Polosa et al., 2011). It is noteworthy that most subjects continue to use e-cigarettes after tobacco reduction or abstinence.

POTENTIAL HEALTH RISKS

The World Health Organization (WHO) noted in 2009 that e-cigarettes "pose significant public health issues and raise questions for tobacco control policy and regulation." The WHO went on further to state, "there is little or no data available on the emissions; their health effects have not been studied; and their marketing and use could undermine public smoking bans, which are important public health interventions." The sales, marketing, and import of these products are banned in a number of countries including Australia, Brazil, Canada, Denmark, Netherlands, Norway, Panama, and Singapore.

The FDA Center for Drug Evaluation and Research (CDER) originally announced that e-cigarettes would be regulated as a "drug delivery device," which would require that each product meet the same safety and efficacy standards as nicotine patches, gums and other smoking cessation products (if e-cigarette companies claim cessation as a therapeutic purpose) before reaching consumers. NJOY, formerly Sottera Inc., successfully sued the FDA in 2009 to not be regulated as a drug delivery device, a move that freed the e-cigarette industry from immediate federal regulation. The court ruled that e-cigarettes were just another tobacco product under the definition provided by the federal Tobacco Control Act, and, as long as they weren't marketed for therapeutic purposes, could be regulated by the FDA Center for Tobacco Products (CTP). If, in the future, the FDA-CTP deems e-cigarettes as subject to the Federal Food, Drug, and Cosmetic Act by regulation, they will be regulated federally as tobacco products under the Tobacco Control Act of 2009.

In 2009, the FDA conducted a laboratory analysis of two widely-marketed e-cigarettes and their findings provided evidence that these products expose users to harmful chemical ingredients, including many of the same toxic and carcinogenic compounds found in conventional cigarettes. Of the other chemicals identified, the FDA has focused on potential health hazards associated with two: tobacco-specific nitrosamines (TSNAs) and diethylene glycol (DEG). Other studies have suggested that only trace amounts of TSNAs are found in e-cigarettes, levels similar to those found in a nicotine patch.

PRO E-CIGARETTE POSITION

- They prevent nicotine withdrawal.
- No tobacco smoke odor or bad breath.
- They mimic the sensation of inhaling smoke. Gestures and actions are similar to smoking, potentially providing craving relief.
- E-cigarettes do not contain the 7,000 plus chemicals known to be in tobacco smoke, and reduce the morbidity and mortality associated with tobacco smoke.
- Second-hand exposure risk may be in the same range as nonsmoking.

CON E-CIGARETTE POSITION

- Limited safety and efficacy data.
- No FDA regulation.
- Unknown long term effects of nicotine delivery systematically to the lungs. Even with the use of the nicotine "inhaler," more than 90 percent of the nicotine is delivered and absorbed in the oral cavity and very little reaches the lungs.
- Some e-cigarette users refill their own cartridges, which may be dangerous because it involves dealing with toxic levels of nicotine. Some refill bottles contain over 1,000 mg of nicotine. The fatal dose for children is estimated at only 10 mg and at 30-60 mg for adults.
- Increased risk of non-smoker exposure to nicotine and the development of nicotine dependence. Except in a few states, e-cigarettes can be marketed and sold to children and young adults. They are marketed to appeal to kids in candy and fruit flavors, like bubblegum and strawberry, and are readily available to youth in malls and online.
- Maintain addictive behaviors.
- Potentially trigger craving in others who see the smoking-like behavior.
- It is a way to get around smoke-free policies that undermines public health interventions.

REFERENCES

Cahna, Z., & Siegel, M. (2010). Electronic cigarettes as a harm reduction strategy for tobacco control: A step forward or a repeat of past mistakes? *Journal of Public Health Policy, 32*(1), 16-31.

Caponnetto, P., Campagna, D., Papale, G., Russo, C., & Polosa, R. (2012). The emerging phenomenon of electronic cigarettes. *Expert Review of Respiratory Medicine, 6*(1), 63-74. doi: 10.1586/ers.11.92

Czogala J., Goniewicz, M. L., Fidelus, B., Zielinka-Danch, W., & Sobczak, A. (2013). Assessment of passive exposure to aerosol from electronic cigarettes [Abstract]. The Society for Research on Nicotine and Tobacco 2013 Annual Meeting, Boston MA, March 2013. Retrieved from http://www.srnt.org/conferences/abstracts/pdfs/SRNT_2013_Abstracts_I-Modified.pdf

Join Together Staff at The Partnership for Drugfree. (2013, April 19). Senators call on FDA to restrict e-cigarette sales and marketing to children. Retrieved from http://www.drugfree.org/join-together/government/senators-call-on-fda-to-restrict-e-cigarette-sales-and-marketing-to-children

King, B. A., Alam, S., Promoff, G., Arrazola, R., & Dube, S. R. (2013). Awareness and ever use of electronic cigarettes among U.S. adults, 2010-2011. *Nicotine & Tobacco Research*, *15*(9), 1623-1627.

Polosa, R., Caponnetto, P., Morjaria, J.B., Papale, G., Campagna, D., & Russo, C. (2011). Effect of an electronic nicotine delivery device (e-cigarette) on smoking reduction and cessation: A prospective 6-month pilot study. *BMC Public Health, 11*(1), 786. doi:10.1186/1471-2458-11-786

U.S. Food and Drug Administration. (2009, May 4). Evaluation of e-cigarettes. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation, Division of Pharmaceutical Analysis. Retrieved from www.fda.gov/downloads/Drugs/ScienceResearch/UCM173250.pdf

World Health Organization. (2009). *WHO study group on tobacco product regulation: Report on the scientific basis of tobacco product regulation: Third report of a WHO study group.* WHO Technical Report Series (Vol. 955). World Health Oganization.

Zhu, S-H, Gamst, A., Lee, M., Cummins, S., Yin, L., & Zoref, L. (2013). The use and perception of electronic cigarettes and snus among the U.S. population [Abstract]. The Society for Research on Nicotine or Tobacco 2013 Annual Meeting, Boston MA, March 2013. Retrieved from http://www.srnt.org/conferences/abstracts/pdfs/SRNT_2013_Abstracts_I-Modified.pdf