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 COMPREHENSIVE CANCER CENTER



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#### Survey: Majority Under 35 Think E-Cigs are Safer, Research Studies Aim to Find Out

Ohio State seeking volunteers who currently use cigarettes, smokeless tobacco or e-cigarettes for two clinical studies aimed at understanding the health effects of e-cigarettes and other tobacco products

COLUMBUS, Ohio -- Most Americans under age 35 think that using electronic cigarettes does not cause as much damage lung health as compared with traditional cigarettes, according to the results of a new national consumer survey.

The survey – which included more than 2,000 people under the age of 35 – showed that 44 percent of survey respondents reported believing that e-cigarettes are less harmful to the lungs than traditional cigarettes. Among men specifically, that number jumped to 54 percent who think e-cigarettes are safer.

"The truth is there is just so much we don't know about these new products," said <u>Peter Shields</u>, MD, a thoracic oncologist, cancer control researcher and deputy director of <u>The Ohio State University Comprehensive Cancer</u> <u>Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute</u>. "We have no idea where in the spectrum these are, in terms of safety. Are they like cigarettes, or nothing like cigarettes? Do they affect people the same if they've never smoked, or a lot worse? We need to figure this out."

#### **Ongoing Clinical Studies Evaluate Health Impact**

The OSUCCC – James is recruiting healthy volunteers who currently use tobacco products for two clinical studies underway to evaluate the health effects of electronic cigarettes (known as "e-cigs" or "vaping") and other tobacco products.

"There is minimal data available regarding the direct health effects of e-cig use or vaping, but these products have gained rapid popularity among existing smokers and non-smokers alike, including young adults," says Shields. "We are concerned that people assume these products have fewer negative health effects as compared with cigarettes and other tobacco products. The reality is that they are still a tobacco product and people are still inhaling potentially harmful chemicals. They should not be considered a 'safer' option until science has the opportunity to catch up with the consumer market."

On May 5, 2016, the U.S. Food and Drug Administration (FDA) finalized a rule extending its regulatory authority to all tobacco products, including e-cigarettes, cigars, hookah tobacco and pipe tobacco. Prior to this, there was no federal law prohibiting retailers from selling e-cigarettes, hookah tobacco or cigars to people under age 18. The final FDA went into effect Aug. 8, 2016.

The OSUCCC – James research is being done to provide the FDA with scientific data to guide consumer regulation of tobacco products. The research is funded by the FDA and the National Cancer Institute.

## PROJECT 1

### Evaluating the Effects of E-Cig Use on Lung Health

The OSUCCC – James is recruiting about 60 current cigarette smokers, e-cig users, smokeless tobacco users, and non-smokers for this pilot study aimed at understanding whether e-cig use impacts lung health differently than traditional cigarettes.

In order to directly assess the impact of tobacco and e-cig use on the lungs, volunteers undergo bronchoscopy. This is an outpatient test where a doctor inserts a thin tube through the nose or mouth to view the airways. A small sample of lung cells will be collected from fluid in the lungs of healthy smokers, e-cig users, smokeless tobacco users and non-smokers to evaluate differences among the groups. Participants will also be asked to complete questionnaires regarding demographic information, medical history and previous/current tobacco use.

"This will allow us to see – in real time – how the lung tissue of non-smokers, e-cig users and traditional cigarette smokers differs. We are especially interested in understanding how e-cig use impacts immunology factors. This could be an important indicator of negative health impacts and give us clues about the changes in lung tissue that lead to future lung diseases," adds Shields.

Non-smoker volunteers will be asked to use nicotine- and flavor-free e-cigs for one month and then undergo another bronchoscopy so that they can document the effects, if any, of e-cigs on the lungs.

All information gathered through the study will be used to evaluate health impact of e-cig use on the lung and help guide the FDA in developing future regulations to make e-cigs safer. Participants do not have to reside in Columbus, Ohio, to participate in the study but they do need to be able to travel to The OSUCCC – James a minimum of two times. Participants will be compensated for their time and receive e-cigs for free.

To learn more, visit cancer.osu.edu/ecigs, email ecig-study@osumc.edu or call 1-844-744-2447.

## PROJECT 2 Carcinogen-Exposure of E-cigs and Cigarettes - Used Together or Separately

The OSUCCC – James is seeking several hundred current smokers who are otherwise in good health for a study to evaluate the impact of e-cigarettes and other tobacco products on exposure to cancer-causing chemicals and other smoke toxins. In addition, researchers will collect information about how flavorings influence a person's choice to use the products. The study is being conducted in partnership with the University of Minnesota and Roswell Park Cancer Institute, and is expected to enroll about 600 patients nationwide over five years.

The study has two phases: a baseline phase and an eight-week clinical trial. During the baseline phase, participants will be asked to complete questionnaires and provide urine and mouth cell samples. They will then be will be randomly assigned to one of the clinical trial study groups: e-cig (delivers vaporized nicotine) or medicinal nicotine (gum or lozenges) for 8 weeks. All participants will receive free products (e-cigs or nicotine replacement therapy) and financial compensation for participation.

"This study is aimed at identifying how different methods of using tobacco impacts the exposures that happen when smoking the product or using e-cigs, but it will also give us important information about how personal thoughts and attitudes toward tobacco products influence how, when and why people use tobacco at all," explains Shields.

Participants do not have to reside in Columbus, Ohio, to participate in this study but they must be able to come to The OSUCCC – James weekly for a period of three months and have access to a telephone.

To learn more about this study, visit cancer.osu.edu/ecigs, email <u>comet-study@osumc.edu</u> or call 1-844-744-2447.

## Funding and Additional Information

Both e-cig studies are funded by the National Institutes of Health and FDA as part of the Ohio State University's Tobacco Center of Regulatory Sciences, a federally funded research program that spans the entire university. The center focuses on research aimed at putting science behind the FDA's regulation of tobacco products. Additional support for the bronchoscopy study comes from Pelotonia, a grassroots cycling event that has raised more than \$106 million for cancer research efforts at The OSUCCC – James. Pelotonia 2017 takes place Aug. 4-6, 2017. Learn more at <u>pelotonia.org</u>.

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# About the OSUCCC – James

The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute strives to create a cancer-free world by integrating scientific research with excellence in education and patient-centered care, a strategy that leads to better methods of prevention, detection and treatment. Ohio State is one of only 46 National Cancer Institute-designated Comprehensive

Cancer Centers and one of only four centers funded by the NCI to conduct both phase I and phase II clinical trials on novel anticancer drugs. As the cancer program's 306-bed adult patient-care component, The James is one of the top cancer hospitals in the nation as ranked by *U.S. News & World Report* and has achieved Magnet designation, the highest honor an organization can receive for quality patient care and professional nursing practice. At 21 floors with more than 1.1 million square feet, The James is a transformational facility that fosters collaboration and integration of cancer research and clinical cancer care. For more information, visit <u>cancer.osu.edu</u>.