

Andrew MacLean RAI Services Inc March 28, 2019



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Press release

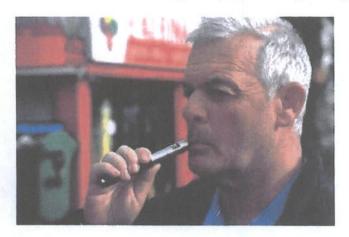
PHE publishes independent expert e-cigarettes evidence review

A new Public Health England (PHE) e-cigarette evidence review, undertaken by leading independent tobacco experts, provides an update on PHE's 2015 review.

Published 6 February 2018

From:

Public Health England (https://www.gov.uk/government/organisations/public-health-england)



The report covers e-cigarette use among young people and adults, public attitudes, the impact on quitting smoking, an update on risks to health and the role of nicotine. It also reviews heated tobacco products.

The main findings of PHE's evidence review are that:

- vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits
- e-cigarettes could be contributing to at least 20,000 successful new quits per year and possibly many more
- e-cigarette use is associated with improved quit success rates over the last year and an accelerated drop in smoking rates across the country

- many thousands of smokers incorrectly believe that vaping is as harmful as smoking; around 40% of smokers have not even tried an e-cigarette
- there is much public misunderstanding about nicotine (less than 10% of adults understand that most of the harms to health from smoking are not caused by nicotine)
- the use of e-cigarettes in the UK has plateaued over the last few years at just under 3 million
- the evidence does not support the concern that e-cigarettes are a route into smoking among young people (youth smoking rates in the UK continue to decline, regular use is rare and is almost entirely confined to those who have smoked)

PHE's evidence review comes just a few weeks after a US National Academies of Sciences, Engineering and Medicine report on e-cigarettes. Their conclusion on e-cigarette safety also finds that based on the available evidence 'e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes.'

Professor John Newton, Director for Health Improvement at PHE said:

Every minute someone is admitted to hospital from smoking, with around 79,000 deaths a year in England alone.

Our new review reinforces the finding that vaping is a fraction of the risk of smoking, at least 95% less harmful, and of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know.

It would be tragic if thousands of smokers who could quit with the help of an e-cigarette are being put off due to false fears about their safety.

Professor Ann McNeill, lead author and Professor of Tobacco Addiction at King's College London said:

It's of great concern that smokers still have such a poor understanding about what causes the harm from smoking. When people smoke tobacco cigarettes, they inhale a lethal mix of 7,000 smoke constituents, 70 of which are known to cause cancer.

People smoke for the nicotine, but contrary to what the vast majority believe, nicotine causes little if any of the harm. The toxic smoke is the culprit and is the overwhelming cause of all the tobacco-related disease and death. There are now a greater variety of alternative ways of getting nicotine than ever before, including nicotine gum, nasal spray, lozenges and e-cigarettes.

Professor Linda Bauld, author and Professor of Health Policy, University of Stirling and Chair in Behavioural Research for Cancer Prevention, Cancer Research UK said:

Concern has been expressed that e-cigarette use will lead young people into smoking. But in the UK, research clearly shows that regular use of e-cigarettes among young people who have never smoked remains negligible, less than 1%, and youth smoking continues to decline at an encouraging rate. We need to keep closely monitoring these trends, but so far the data suggest that e-cigarettes are not acting as a route into regular smoking amongst young people.

PHE is calling on smokers and a number of bodies to act on the evidence.

Smokers

Anyone who has struggled to quit should try switching to an e-cigarette and get professional help. The greatest quit success is among those who combine using an e-cigarette with support from a local stop smoking service.

Local stop smoking services and healthcare professionals

These should provide behavioural support to those smokers wanting to quit with the help of an ecigarette. A new training course on e-cigarettes for healthcare professionals by the National Centre for Smoking Cessation and Training is now live.

Medicines and Healthcare products Regulatory Agency (MHRA)

MHRA continue their work in regulating and licensing e-cigarette products and support manufacturers to expedite the licensing of e-cigarettes as medicinal quit aids. PHE believes there is compelling evidence that e-cigarettes be made available to NHS patients.

NHS Trusts

To become truly smokefree, Trusts should ensure

- · e-cigarettes, alongside nicotine replacement therapies are available for sale in hospital shops
- vaping policies support smokers to quit and stay smokefree
- smoking shelters be removed
- · frontline staff take every opportunity to encourage and support patients to quit

The government's new Tobacco Control Plan for England includes a commitment to 'maximise the availability of safer alternatives to smoking'. It makes clear that e-cigarettes have an important part to play in achieving the ambition for a smokefree generation.

Background

- Read the report commissioned by PHE Evidence review of e-cigarettes and heated tobacco products (https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidencereview) - McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018).
- 2. Over the past few years, e-cigarette use has hovered at just under 6% of the adult population in Britain. The most common reason for e-cigarette use continues to be to help with quitting and they are the most popular quitting tool in England. At the same time, quit success rates have been improving and we are also seeing an accelerated drop in smoking rates (currently 15.5% in England): smokinginengland.info/latest-statistics (http://www.smokinginengland.info/latest-statistics/).
- 79,000 people in England die every year as a result of smoking, and over half of long-term smokers will die from a smoking-related illness if they do not quit: digital.nhs.uk/catalogue/PUB24228 (https://digital.nhs.uk/data-andinformation/publications/statistical/statistics-on-smoking/statistics-on-smoking-england-2017-pas).
- PHE 2015 e-cigarettes evidence review: McNeill A., P. Hajek et al, E-cigarettes an evidence update: A report commissioned by Public Health England (https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update), Public Health England, August.
- Authors'note (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/456704/McNeill-Hajek_report_authors_note_on_evidence_for_95_estimate.pdf) on evidence for 'around 95% safer' estimate.
- Nicotine without smoke: tobacco harm reduction (https://www.rcplondon.ac.uk/projects/outputs/nicotinewithout-smoke-tobacco-harm-reduction-0), Royal College of Physicians, April 2016.
- 7. Smoking Toolkit Study (http://www.smokinginengland.info/).
- ASH (May 2017) Use of e-cigarettes (vapourisers) among adults in Great Britain (http://ash.org.uk/information-and-resources/fact-sheets/use-of-e-cigarettes-among-adults-in-great-britain-2017/).
- Bauld, Linda, Anne Marie MacKintosh, Brian Eastwood, Allison Ford, Graham Moore, Martin Dockrell, Deborah Arnott, Hazel Cheeseman, and Ann McNeill. 'Young people's use of ecigarettes across the United Kingdom: Findings from five surveys 2015–2017.' (https://www.ncbi.nlm.nih.gov/pubmed/28850065) International journal of environmental research and public health 14, no. 9 (2017): 973.
- Towards a Smokefree Generation: A Tobacco Control Plan for England
 (https://www.gov.uk/government/publications/towards-a-smoke-free-generation-tobacco-control-plan-for-england)
 Department of Health, July 2017.
- NHS Digital, Statistics on Smoking: England, 2017 (https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-smoking/statistics-on-smoking-england-2017-pas).
- US National Academies of Sciences, Engineering, and Medicine (January 2018) Public Health Consequences of E-Cigarettes (http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx).

About Public Health England

Public Health England (https://www.gov.uk/phe) exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, knowledge and intelligence, advocacy, partnerships and providing specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific expertise and support. Follow us on Twitter: @PHE_uk (https://twitter.com/PHE_uk) and Facebook: www.facebook.com/PublicHealthEngland (https://www.facebook.com/PublicHealthEngland).

Public Health England press office

Email phe-pressoffice@phe.gov.uk

Telephone 020 7654 8400

Out of hours telephone 020 8200 4400

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A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy

Peter Hajek, Ph.D., Anna Phillips-Waller, B.Sc., Dunja Przulj, Ph.D., Francesca Pesola, Ph.D., Katie Myers Smith, D.Psych., Natalie Bisal, M.Sc., Jinshuo Li, M.Phil., Steve Parrott, M.Sc., Peter Sasieni, Ph.D., Lynne Dawkins, Ph.D., Louise Ross, Maciej Goniewicz, Ph.D., Pharm.D., Qi Wu, M.Sc., and Hayden J. McRobbie, Ph.D.<u>et al.</u>

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Abstract

BACKGROUND E-cigarettes are commonly used in attempts to stop smoking, but evidence is limited regarding their effectiveness as compared with that of nicotine products approved as smoking-cessation treatments.

METHODS We randomly assigned adults attending U.K. National Health Service stop-smoking services to either nicotine-replacement products of their choice, including product combinations, provided for up to 3 months, or an e-cigarette starter pack (a second-generation refillable e-cigarette with one bottle of nicotine e-liquid [18 mg per milliliter]), with a recommendation to purchase further e-liquids of the flavor and strength of their choice. Treatment included weekly behavioral support for at least 4 weeks. The primary outcome was sustained abstinence for 1 year, which was validated biochemically at the final visit. Participants who were lost to follow-up or did not provide biochemical validation were considered to not be abstinent. Secondary outcomes included participant-reported treatment usage and respiratory symptoms.

RESULTS A total of 886 participants underwent randomization. The 1-year abstinence rate was 18.0% in the e-cigarette group, as compared with 9.9% in the nicotine-replacement group (relative risk, 1.83; 95% confidence interval [CI], 1.30 to 2.58; P<0.001). Among participants with 1-year abstinence, those in the e-cigarette group were more likely than those in the nicotine-replacement group to use their assigned product at 52 weeks (80% [63 of 79 participants] vs. 9% [4 of 44 participants]). Overall, throat or mouth

irritation was reported more frequently in the e-cigarette group (65.3%, vs. 51.2% in the nicotinereplacement group) and nausea more frequently in the nicotine-replacement group (37.9%, vs. 31.3% in the e-cigarette group). The e-cigarette group reported greater declines in the incidence of cough and phlegm production from baseline to 52 weeks than did the nicotine-replacement group (relative risk for cough, 0.8; 95% CI, 0.6 to 0.9; relative risk for phlegm, 0.7; 95% CI, 0.6 to 0.9). There were no significant betweengroup differences in the incidence of wheezing or shortness of breath.

CONCLUSIONS E-cigarettes were more effective for smoking cessation than nicotine-replacement therapy, when both products were accompanied by behavioral support. (Funded by the National Institute for Health Research and Cancer Research UK; Current Controlled Trials number, ISRCTN60477608.)

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Funding and Disclosures

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American Cancer Society Position Statement on Electronic Cigarettes

The American Cancer Society Board of Directors approved the following position statement on electronic cigarettes (ecigarettes) in February 2018. The position statement will be used to guide ACS's tobacco control and cessation efforts as it relates to these products.

ACS Position Statement on Electronic Cigarettes

Combustible tobacco products, primarily cigarettes, are the single greatest cause of cancer and kill about 7 million people worldwide each year. In the United States, 98% of all tobacco-related deaths are caused by cigarette smoking. The U.S. tobacco landscape has changed rapidly in recent years, with millions of consumers now using electronic nicotine delivery systems (ENDS), the most prominent of which are electronic cigarettes (e-

cigarettes). E-cigarettes contain heated nicotine extracted from tobacco, as well as a variety of flavorings and other additives.

Scientific Summary: Based on currently available evidence, using current generation e-cigarettes is less harmful than smoking cigarettes, but the health effects of long-term use are not known. The American Cancer Society (the ACS) recognizes our responsibility to closely monitor and synthesize scientific knowledge about the effects of all tobacco products, including e-cigarettes and any new products derived from tobacco. As new evidence emerges, the ACS will promptly report these findings to policy makers, the public and clinicians.

Clinical Recommendations: The ACS has always supported any smoker who is considering quitting, no matter what approach they use; there is nothing more important that they can do for their health. To help smokers quit, the ACS recommends that clinicians advise their patients to use FDA-approved cessation aids that have been proven to support successful quit attempts. Many smokers choose to quit smoking without the assistance of a clinician and some opt to use ecigarettes to accomplish this goal. The ACS recommends that clinicians support all attempts to quit the use of combustible tobacco and work with smokers to eventually stop using any tobacco product, including e-cigarettes. Some smokers, despite firm clinician advice, will not attempt to quit smoking cigarettes and will not use FDA approved cessation medications. These individuals should be encouraged to switch to the least harmful form of tobacco product possible; switching to the exclusive use of e-cigarettes is preferable to continuing to smoke combustible products. Of course, these individuals should be regularly advised to completely quit using all tobacco products. The ACS strongly discourages the concurrent (or "dual") use of e-cigarettes and combustible cigarettes, a behavior that is far more detrimental to a person's health compared to the substantial health benefit of quitting smoking.

Policy Recommendations: The American Cancer Society recommends implementing polices and public health measures known to prevent the initiation and use of all tobacco products, including appropriate taxation, retail policies (e.g., raising the minimum age of purchase to 21), tobacco and e-cigarette aerosol-free policies and funding of evidence-based prevention and cessation programs. The ACS strongly recommends that every effort be made to prevent the initiation of e-cigarettes by youth. The use of products containing nicotine in any form among youth is unsafe and can harm brain development. Furthermore, evidence indicates that young e-cigarette users are at increased risk for both starting to smoke and becoming long-term users of combustible tobacco products.

The ACS encourages the FDA to regulate all tobacco products, including e-cigarettes, to the full extent of its authority, and to determine the absolute and relative harms of each product. The FDA should assess whether ecigarettes help to reduce tobacco-related morbidity and mortality, and the impact of marketing of e-cigarettes on consumer perceptions and behavior. Any related regulatory regime should include post-marketing surveillance to monitor the long-term effects of these products and ensure the FDA's actions have the intended health outcome of significantly reducing disease and death. Furthermore, the FDA should use its authorities to reduce the toxicity, addictiveness and appeal of tobacco products currently on the market. The ACS also applauds the FDA for recognizing its significant role as a sciencebased agency in helping to address the addictiveness of nicotine in cigarettes. Reducing nicotine in all combustible tobacco products to below addictive levels holds the potential to significantly accelerate reductions in the use of combustible tobacco products, which remain by far the leading preventable cause of cancer and preventable death in the United States.

Statement issued February 15, 2018

→ MORE IN STAY HEALTHY ⊢

Stay Away From Tobacco

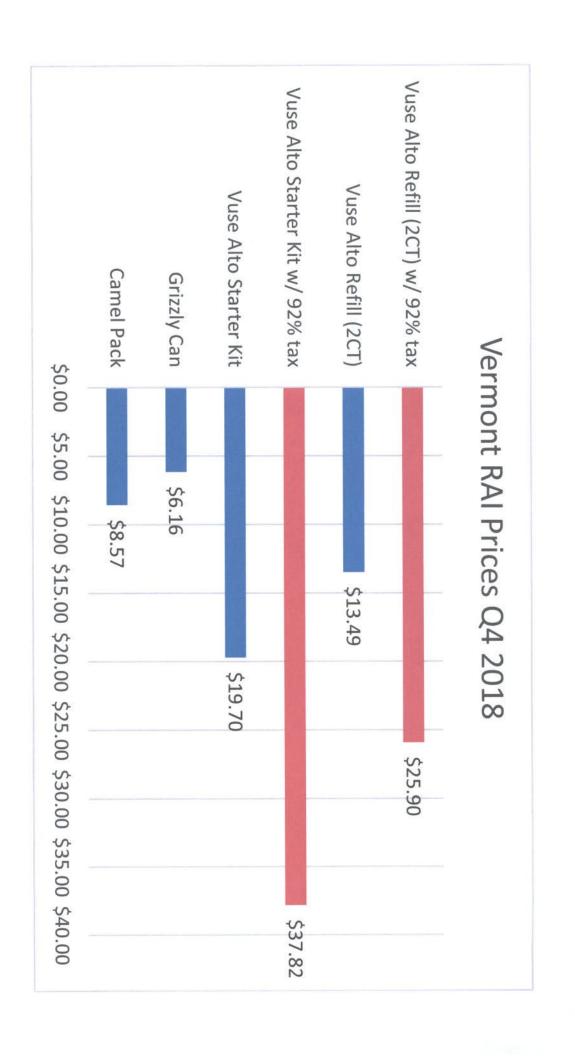
Be Safe in the Sun

Eat Healthy and Get Active

Protect Against HPV

Cancer Screening Guidelines

Exams and Tests



Lifetime Cigarette Use, Even 1 or 2 Puffs

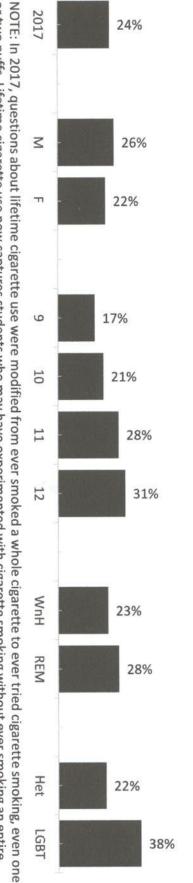
Overall, a quarter of high school students have ever tried a cigarette, even one or two puffs; 8% tried a cigarette before age 13.

Male students are significantly more likely than female students to try smoking a cigarette (26% vs 22%) and were more like to try one before age 13 (9% vs 6%).

New in 2017

- Ever trying a cigarette significantly increases with each grade level
- Students of color significantly more likely than white, non-Hispanic students to try a cigarette (38% vs 22%) or to use one before age 13 (12% vs 7%)
- LGBT students are significantly more likely to ever try smoking (28% vs 23%) and were twice as likely to try a cigarette before age 13 (7% vs 14%).

Lifetime Cigarette Use, Even 1 or 2 Puffs



cigarette. Data on lifetime cigarette use cannot be compared with previous results. or two puffs. Lifetime cigarette use now captures students who may have experimented with cigarette smoking without ever smoking an entire

Lifetime Use of Electronic Vapor Products

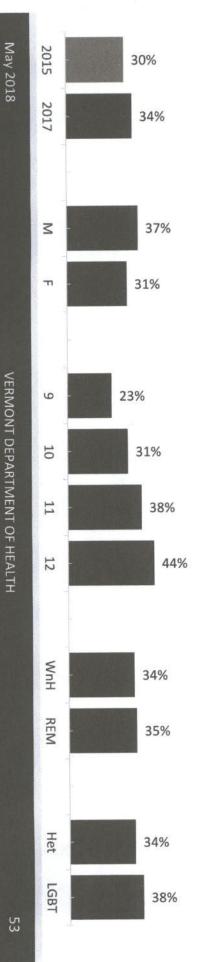
Common products include: blu, NJOY, Vuse, MarkTen, Logic, Vapin Plus, eGo, and Halo. Electronic vapor products (EVP) include e-cigarettes, e-cigars, e-pipes, vape pipes, vaping pens, e-hookahs, and hookah pens.

In 2017, a third of students (34%) ever tried an electronic vapor product (EVP).

The percent of students who have ever tried an electronic vapor product has significantly increased since first asked in 2015.

- Male students are significantly more likely than female students to have ever tried an EVP.
- Ever trying an EVP significantly increases with each grade level. Students in vapor product. 12th grade are nearly two times a likely as 9th graders to ever try an electronic
- Ever using an EVP does not differ by race.
- LGBT students are significantly more likely to ever try an EVP compared to heterosexual/cisgender students.

Lifetime Use of Electronic Vapor Products



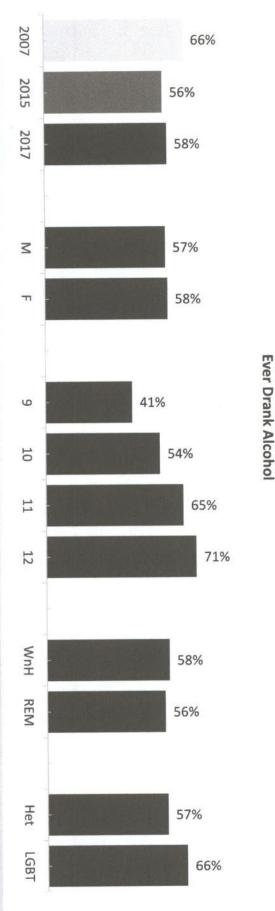
Lifetime Alcohol Use

Among high school students, three in five have ever had alcohol; one in seven (14%) drank before age 13.

The percent of students who have ever drank alcohol significantly decreased over the last decade, from 66% in 2007 to 58% in 2017. However, from 2015 to 2017 the percent ever drinking alcohol significantly increased (56% vs. 58%).

Following a similar trend, alcohol use before age 13 has significantly decreased since 2007 (19%), but increased from 2015 (12%) to 14% in 2017.

- Ever drinking alcohol does not differ by sex or race. Male students and students of color are significantly more likely than female students and white, non-Hispanic students to try alcohol before age 13 (16% vs 11% and 21% vs 12%, respectively)
- Lifetime alcohol use significantly increases with each grade level. By the time students are in their senior year, nearly three-quarters have tried alcohol. Ninth grade students are significantly more likely to have tried alcohol before age 13 compared to older students (17% vs 13% vs 13% vs 11%).
- LGBT students are significantly more likely than heterosexual/cisgender students to consume alcohol in their lifetime (shown below) and to drink alcohol before age 13 (20% vs 13%).



Lifetime Marijuana Use

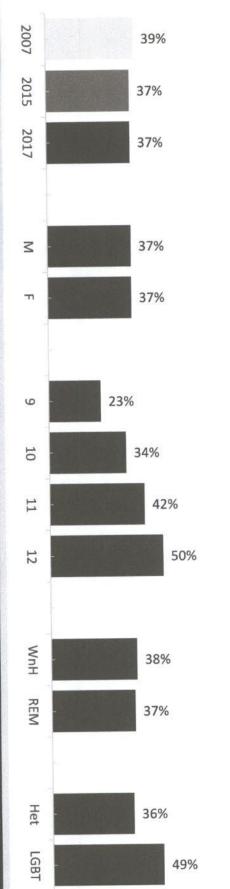
Overall, 37% of students have ever used marijuana; 6% used it before age 13.

Ever using marijuana has remained relatively stable over the past decade; however, during that timeframe, significantly fewer students reported using marijuana before age 13 (9% vs 6%).

Lifetime marijuana use and use before age 13 did not change between 2015 and 2017.

- Lifetime marijuana use does not differ by sex or race.
- Using marijuana before age 13 is significantly higher among male students compared to female students (7% vs 5%) and students of color (10% vs 5%).
- Half of all seniors have ever tried marijuana. Ever using marijuana significantly increases with each grade level; using it before age 13 does not vary by grade.
- LGBT students are significantly more likely to report ever using marijuana (shown below) and to try it before age 13 (11% vs 5%), compared to heterosexual/cisgender students.

Ever Used Marijuana



May 2018