Effects of reduced-risk nicotine-delivery products on smoking prevalence and cigarette sales: an observational study

Francesca Pesola,[1] Anna Phillips-Waller,[1*] Emma Beard,[2] Lion Shahab,[2] David Sweanor,[3] Martin Jarvis[2] and Peter Hajek[1]

[1]Wolfson Institute of Population Health, Queen Mary University of London, London, UK
[2]University College London, Tobacco and Alcohol Research Group, Department of Behavioural Science and Health, London, UK
[3]Faculty of Law and Centre for Health Law, Policy and Ethics, University of Ottawa, Ottawa, Canada

[*]Corresponding author a.phillips-waller@qmul.ac.uk

Disclosure of interests of authors

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR journals Library report publication page at https://doi.org/10.3310/RPDN7327.

Primary conflict of interest:

Peter Hajek has provided consultancy to and received research funding from Pfizer.

Lion Shahab has received honoraria for talks, an unrestricted research grant and travel expenses to attend meetings and workshops from Pfizer and an honorarium to sit on an advisory panel from Johnson&Johnson, both pharmaceutical companies that make smoking-cessation products. He has acted as paid reviewer for grant-awarding bodies and as a paid consultant for health-care companies. Other research has been funded by the government, a community-interested company (National Centre for Smoking Cessation) and charitable sources.

David Sweanor has received travel expenses for conferences to the Tobacco Harm Reduction – Challenges and Opportunities in the 21st Century conference (Tbilisi) and The Global Forum on Nicotine conference (Warsaw). He is an unpaid member on committees for pedestrian and cyclist issues and civil liberties. He is Chair of the advisory board of the Centre for Health Law, Policy and Ethics at the University of Ottawa, an adjunct law professor at the same university, on a global advisory committee for the Boston University School of Public Health, and belongs to/advises/funds groups working on a wide range of topics (e.g. nicotine, public health, transportation policy, homelessness, active transportation: all unpaid).

All other authors have no conflicts to disclose.

Published September 2023
DOI: 10.3310/RPDN7327

Scientific summary

Effects of reduced-risk nicotine-delivery products on smoking prevalence and cigarette sales: an observational study

Public Health Research 2023; Vol. 11: No. 7
DOI: 10.3310/RPDN7327

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

The key controversy surrounding reduced-risk alternative nicotine-delivery products (ANDs), comprising electronic cigarettes (ECs), snus and heated tobacco products (HTPs), concerns their effects on smoking prevalence. They may promote smoking by enticing adolescents to cigarette use and by reducing quitting in smokers (e.g. by allowing them to circumvent smoke-free regulation), but it is also possible that ANDs redirect young nicotine seekers away from smoking and help smokers quit, or they may have no clear impact on smoking.

Alternative nicotine-delivery systems have been used for a number of years, and some information may already exist in data on smoking prevalence and on AND and cigarette sales that can contribute to answering this question. If, in countries with substantial AND use, the trends in the historical decline in smoking rates and cigarette sales have slowed down or reversed, and this is not happening in countries that restrict or ban ANDs, this would be consistent with the 'gateway into smoking' hypothesis, while the opposite finding would suggest that these products are replacing rather than promoting smoking. A finding that ANDs have no net effect on smoking prevalence and cigarette sales, or that currently available data do not provide a clear answer, would also have implications both for policies (which will need to take account of the uncertainty) and for future research (which can aim to fill the gaps).

Objectives

We aimed to answer the following research questions (RQs):

RQ1. Is there an association between the prevalence of smoking and prevalence of AND use (in the population in general, in young adults and in different socioeconomic groups), in different countries and for different AND products?

RQ2. Is there an association between sales of different AND products and cigarette sales?

RQ3. Are there any differences in time trends of smoking prevalence (overall, in young adults and in different socioeconomic groups) and cigarette sales following the introduction of ANDs between countries that had similar tobacco control measures prior to ANDs emerging locally, but that have allowed EC sales [United Kingdom (UK) and United States of America (USA)] or banned them (Australia)?

Methods

We examined data from the countries and data sets described below that allow examinations of links between AND use and smoking rates, and between cigarette and AND sales. We also compared trajectories of smoking prevalence over time in countries with contrasting legislative and policy frameworks concerning ANDs.

Countries selected

Regarding prevalence data (RQ1), we explored links between the prevalence of EC use and cigarette smoking in the UK and USA (where data on EC use and cigarette use are available), Sweden (the only EU country where snus use is allowed and where data on snus and cigarette use are available) and Japan (where in addition to smoking prevalence data, at least some data on HTP use are available). We also

looked at links between prevalence of smoking and sales of ANDs in Japan and South Korea, where data on HTP sales were available.

Regarding sales data (RQ2), we explored links between sales of cigarettes and snus in Sweden, and between sales of cigarettes and sales of HTPs in Japan and South Korea.

No comprehensive data on EC sales are available for the UK and USA, because ECs are produced by a large number of manufacturers, but we looked at 'hybrid' links between the prevalence of EC use and sales of cigarettes in the UK and USA.

We also explored whether time trends in cigarette use and sales in the UK and USA, where ECs are allowed, differ from those in Australia, where sales of nicotine-containing ECs are banned (RQ3). The three countries have a broadly similar history and formats of tobacco control otherwise.

Data sources

Where more than one survey was available per country, we selected the survey to use based on:

1. quality of smoking and AND use measures
2. years covered
3. representativeness of samples and weighting
4. number of time points (monthly/quarterly breakdown)
5. sample size
6. quality of socioeconomic status (SES) information.

For the UK, we used the Health Survey for England (HSE) for prevalence and HM Revenue and Customs National Statistics Tobacco Bulletin for cigarette sales data.

For the USA, we used the National Health Interview Survey (NHIS) and the National Youth Tobacco Survey (NYTS) for prevalence of smoking. NielsenIQ data on cigarette sales were purchased from Chicago Booth.

For Australia, we used the National Drug Strategy Household Survey (NDSHS) for prevalence of smoking and Euromonitor International reports for cigarette sales data.

For Japan, we used the National Health and Nutrition Survey for prevalence, Tobacco Institute of Japan data for cigarettes sales and Philip Morris International reports for HTP sales data.

For South Korea, we used the Korea National Health and Nutrition Examination Survey (KHANES) for prevalence, and Korea Tobacco and Ginseng Corporation (KT&G) reports for sales data.

For Sweden, we used the Swedish Council for Information on Alcohol and Other Drugs (CAN): Monitor Studies for prevalence and Swedish Match AB provided data for cigarette and snus sales directly by e-mail. See *Chapter 2 – Methods*, *Survey data chosen* for details of where these surveys were available.

For analyses looking at the interplay between cigarettes and EC/HTP use (RQ1), we included data on smoking from 2005 until the most recent available year up to 2019, before the COVID-19 epidemic started. The same timeframe was used, where available, for analyses exploring the interplay of cigarettes and EC/HTP sales (RQ2). This allowed for modelling of smoking and cigarette sales for at least 5 years prior to the emergence of these newer products. For snus, we analysed the data from 2007 to 2019.

For analyses looking at trends in cigarette smoking in the UK, USA and Australia we used data from 2004 onwards as the NDSHS is triennial and we wanted to include 2004 as a proxy for 2005. Similarly, for the NYTS, which used to be biannual, we included 2004 as a proxy for 2005. For analyses looking at

trends in cigarette sales for the UK, USA and Australia we looked at data from 2010 as sales data for Australia were only available from that year.

Statistical methods

We pre-specified in our statistical analysis plan that we would use dynamic time series applying generalised least squares (GLS) models to explore the association between prevalence of smoking and product use, as well as cigarette and product sales. Regression models were used to compare trends in smoking prevalence between countries where EC use is allowed or banned.

The analyses were adjusted for two policy variables which are believed to have the strongest effect on smoking prevalence and cigarette sales and that have been implemented at different time points in most countries: the introduction of bans on smoking in public spaces where they occurred during the study period; and increases in cigarette prices exceeding normal trends (25% increase in 2010 in Australia, 37% in October 2010 in Japan, 80% increase in 2015 in South Korea, 14% increase in 2009 in the USA and 11% increase in 2015 in the UK). Each policy was modelled as a step level change, coded as one after the introduction of the policy and zero before.

Unfortunately, the available data had insufficient data points for robust time series analyses. We carried out the planned analyses to adhere to the original plan, but the results need to be considered as only tentative and interpreted cautiously. Due to the short time series, it is possible that underlying trends were not correctly identified and removed, resulting in confounding. For example, in the majority of analyses, trends were identified as linear and first-order differencing was used. However, studies suggest that the decline in smoking prevalence follows a more monotonic curvilinear decline over time, which was not identified in the short series and would have required higher differencing. Conversely, with short-term non-granular time series, there is a risk of removing trends which in fact reflect short-term changes and perhaps a casual association between series.

In addition, because of the short series, more sophisticated time series models, such as autoregressive integrated moving average with explanatory variable (ARIMAX), could not be used for the majority of analyses because these require more time-points. ARIMAX models have several benefits over GLS, including the use of transfer functions to model lags between multiple time series and inclusion of seasonal autocorrelation.

Finally, short time series are highly influenced by outliers, and these can dominate the output from models. Longer time series are not influenced in the same way. These factors can all result in spurious associations.

We used Bayes factors (BF) to help us to determine whether non-significant results provided evidence of no effect or were due to data being insensitive, with BF between 1/3 and 1 suggesting no or weak evidence for the null hypothesis, BF between 1/3 and 1/10 suggesting moderate evidence, and 1/10 or lower as strong evidence for the null hypothesis.

Results

Only a few associations were detected. Regarding RQ1, we did not find an association between rates of smoking and rates of alternative nicotine product use, potentially due to the analyses being under-powered. Regarding RQ2, the increase in sales of HTPs in Japan was accompanied by a decrease in sales of cigarettes ($b = -1.09$, $p < 0.001$), suggesting that HTPs are competing with cigarettes rather than facilitating their use. Regarding RQ3, the decline in smoking prevalence seems to have been slower in Australia than in the UK overall (b difference = 0.04, 95% CI 0.02 to 0.06), and slower than in both the UK (b difference = 0.09, 95% CI 0.01 to 0.17) and USA (b difference = 0.07, 95% CI 0.01 to 0.13) among young people, and also among people in lower socioeconomic groups (UK vs. Australia:

b difference = 0.04, 95% CI 0.02 to 0.06; USA vs. Australia: *b* difference = 0.07; 95% CI 0.05 to 0.09). The decline in cigarette sales has also accelerated faster in the UK than in Australia (*b* difference = 0.06, 95% CI 0.04 to 0.08). This suggests that regulations that allow sales of alternative products may result in a reduction rather than an increase of smoking. However, for most results, negative and positive, BF indicated that the evidence was inconclusive.

Limitations

Most of the available data had insufficient data points for robust time series analyses and so the results need to be considered as tentative. One step in time series analysis is the modelling or removal of underlying long-term trends. With short time series and product interaction scenarios, however, it is possible that trends were incorrectly specified and true product interactions were removed. The ecological nature of some of the comparisons limits the causal inferences that can be made and represents another study limitation. Smokers rarely fully switch to alternative nicotine products straight away, which means that prevalence figures for smoking and alternative product use overlap. Longer time periods are needed for a clearer picture of product replacement or product facilitation to emerge.

Conclusions

We detected some indications that ANDs are replacing cigarettes rather than encouraging smoking, but due to limitations listed above, these findings are only tentative. At this time point, concerns that ANDs promote smoking, especially among young people, seem unfounded, but the degree to which access to ANDs can reduce rates of smoking in the population remains unclear. The analyses will become more informative as further data accrue on the prevalence of AND use and smoking and especially on interactions between sales of these products.

Registration

The project is registered on Open Science Framework https://osf.io/bd3ah.

Funding

This project was funded by the National Institute for Health and Care Research (NIHR) Public Health Research programme (NIHR129968) and will be published in full in *Public Health Research*; Vol. 11, No. 7. See the NIHR Journals Library website for further project information.

Public Health Research

ISSN 2050-4381 (Print)

ISSN 2050-439X (Online)

Public Health Research (PHR) was launched in 2013 and is indexed by Europe PMC, NCBI Bookshelf, DOAJ, INAHTA and Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and MEDLINE.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full PHR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/phr.

Criteria for inclusion in the *Public Health Research* journal

Reports are published in *Public Health Research* (PHR) if (1) they have resulted from work for the PHR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Public Health Research* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

PHR programme

The Public Health Research (PHR) programme, part of the National Institute for Health and Care Research (NIHR), is the leading UK funder of public health research, evaluating public health interventions, providing new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The scope of the programme is multidisciplinary and broad, covering a range of interventions that improve public health.

For more information about the PHR programme please visit the website: https://www.nihr.ac.uk/explore-nihr/funding-programmes/public-health-research.htm

This report

The research reported in this issue of the journal was funded by the PHR programme as project number NIHR129968. The contractual start date was in November 2020. The final report began editorial review in August 2022 and was accepted for publication in March 2023. The authors have been wholly responsible for all data collection, analysis and interpretation and for writing up their work. The PHR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).