



Japan EC Seminar (September 20th, 2018)

New evidence on e-cigarettes

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Declaration of interest

- I have no links with any e-cigarette or tobacco manufacturers
- My research into safety and effects of EC is funded by the National Institute of Health Research, Public Health England, UK Centre for Tobacco and Alcohol Studies and UK Medicines Regulatory Agency

Developments since 2016

- Controversy continues
- New nicotine delivery products
- New data on safety
- New data on 'gateway hypothesis'
- New data on effects on smokers
- What to tell smokers
 - If time allows: Varenicline for dual users

Controversy continues

- Pragmatic stance: E-cigarettes (EC) and other lower risk products can reduce smoking-related death and disease
- Moralist (abstinence-only) stance: Lower risk products are a threat to the goal of eradicating nicotine use

Some changes over the past two years

- WHO remains anti-vaping and developing countries that take WHO advice ban EC (Cambodia, Brazil, Egypt etc.)
- Australia and Japan ban EC with nicotine (but Japan allows HnB)
- New Zealand and Canada are lifting bans, Iceland refused EC-hostile TPD
- UK now supports smokers wishing to switch to vaping

Stoptober 2017, PHE Report 2018, Parliament Enquiry 2018



Science and Technology Committee

E-cigarettes inquiry

Public Health England

Protecting and improving the nation's health

Evidence review of e-cigarettes and heated tobacco products 2018 A report commissioned by Public Health England

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Conclusions of UK reviews

- Vaping is likely to be at least 95% less risky than smoking over long-term use
- So far, there is no evidence that EC provide a gateway to smoking for young people
- Vaping regulation should be riskproportionate
- Smokers who cannot/do not want to quit should be encouraged to switch to vaping

Time will tell

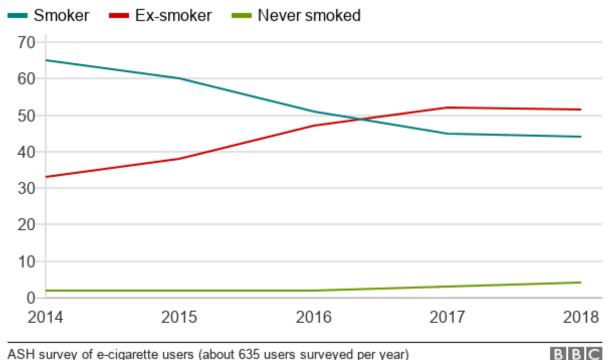
- If lower risk products (ENDS) are a gateway to smoking and risky, ENDSfriendly countries will see increase in smoking and in smoking and ENDS-use related diseases
- If the UK interpretation of evidence is correct, smoking rates and smokingrelated morbidity will go the opposite way, as it did in Sweden with snus

UK experience so far

- 2015: 850,000 smokers switched to vaping plus 710,000 stopped both, smoking rate dropped to 16.9%
- 2016: Smoking prevalence 15.8%
- 2017: Smoking prevalence 14.9%, biggest drops in 18-24 year olds
- 2018: 3.2 million vapers, most stopped smoking
- Eurobarometer 2017: UK now second lowest smoking prevalence in EU (Sweden 5% daily-due to Snus)

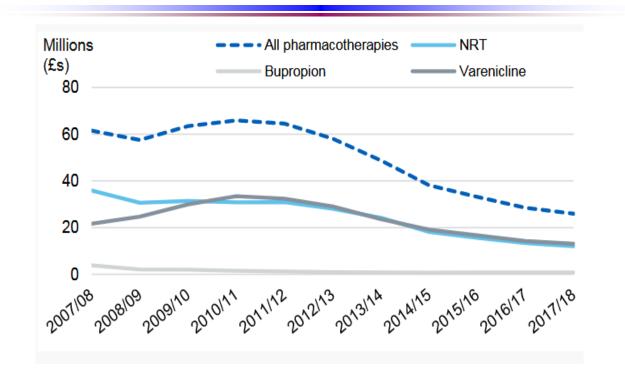
Who uses e-cigarettes?

Percentage of users by smoking status, Great Britain



ASH survey of e-cigarette users (about 635 users surveyed per year)

Saving NHS money

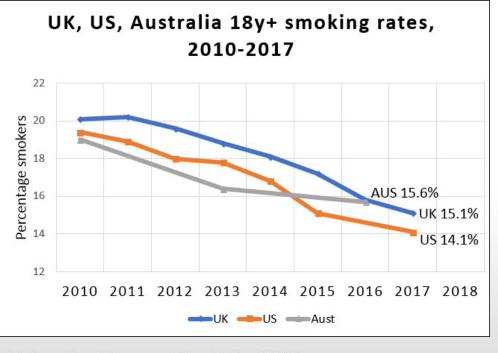


Eurobarometer 2017

- 7% of ex-smokers in EU quit with all licensed meds together
 - Some available for >35 years and widely recommended and used in all EU countries
- 6% quit with EC (at no cost to health care systems)

Special Eurobarometer 458, 2017

Smoking in countries that allow (UK and US) and ban (Australia) vaping

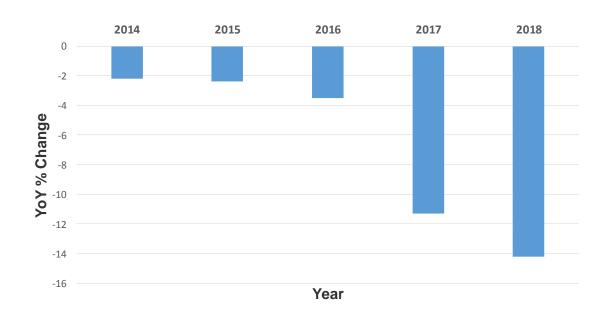


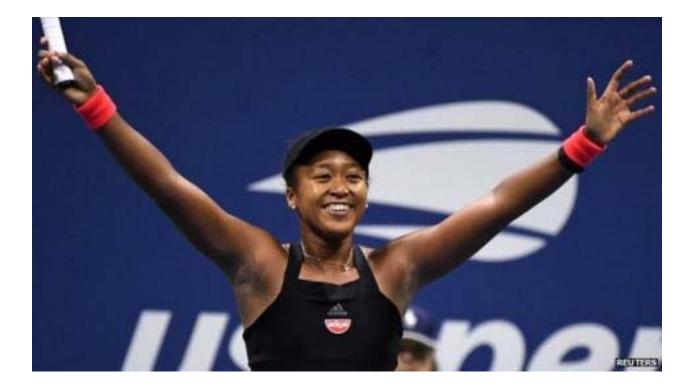
UK. Annual Population survey, Office of National Statistics US. National Health Interview Survey, <u>Centers</u> for Disease Control and Prevention Australia. National Drug Strategy Household Survey, Australian Institute of Health and Welfare

HnB is reducing cigarette smoking in Japan

- Advertising and information about lower risk is allowed; no EC with nicotine so HnB has no low risk competition
- January-July total domestic cigarette sales declined by 24% compared to the same period in 2016
- From a typical rate of decline (2-3% per year) to unprecedented (11-14% per year), may be slowing down now
 Japanese Domestic Cigarette Sales Results for July 2018

Cigarette sales decline Japan 2014-2018





Tobacco industry

- Will eventually have to switch to low risk products. Bets on HnB, did not manage to keep pace with EC innovations
- 'Barriers to entry' and bans on EC protect cigarettes from EC competition and keep smoking alive. In this sense, WHO and regulators in some countries (FDA) are helping TI interests

Developments in ENDS products since 2016

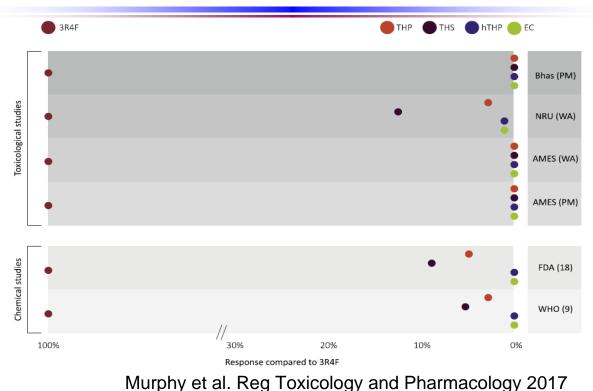
Heat not Burn products

- Philip Morris' iQOS
- Extensive research by PM and some independent data

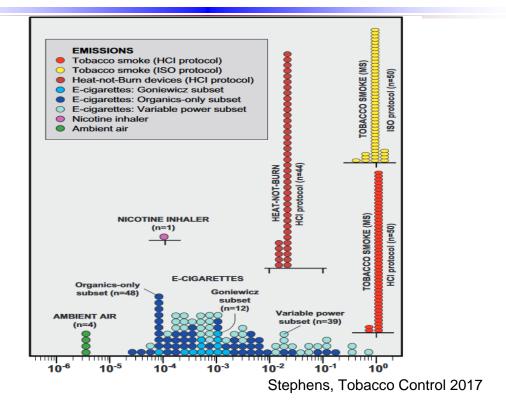


- Not as safe as EC, likely to be more addictive, but much less risky than cigarettes
- If regulators strangle EC, this will be the (tobacco industry dominated) future

Toxin levels in cigarettes, EC and HNB (industry data)



Independent assessment of relative cancer potency



New review

- HnB expose users and bystanders to substantially fewer harmful compounds than cigarettes.
- The evidence is primarily from tobacco industry data
- The HnB harm profile needs to be compared with other alternative nicotine products that have reduced health risk exposure profiles.

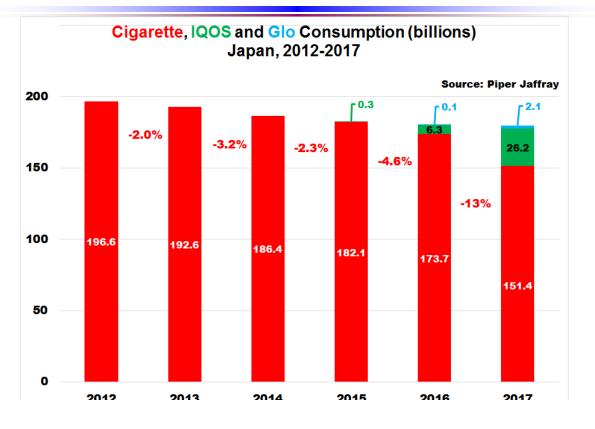
IQOS is allowed to inform smokers about relative risks



GLO British American Tobacco



Cigarettes, IQOS and GLO use in Japan



An interesting curio

 An unsuccessful murder attempt by putting mercury in an HnB product

Hitosugi et al. Int J Legal Med. 2018

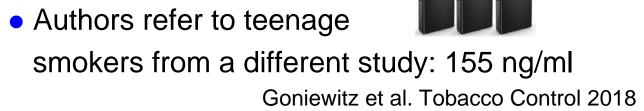
Juul PAX Labs/Juul Labs (not TI)

- 'Vaporizer' using nicotine salt, launched in US in 2016
- 50mg/ml nicotine, 200 puffs
- Seems more effective than other ECs – huge sales
- UK version only 19mg/ml
- First study of nicotine delivery



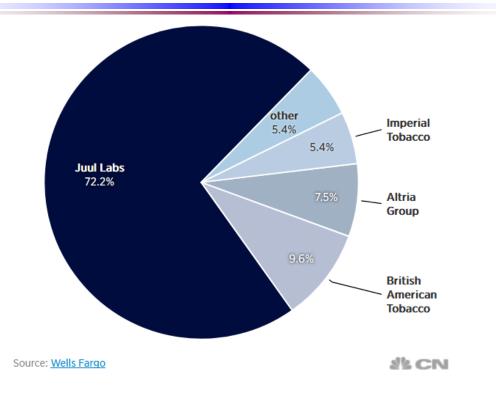
Urine cotinine in Juul users

- N=22, <21 year olds who used Juul in past week
- 245 ng/ml (no NNAL)



But adult daily smokers: 1,448 ng/ml

Juul outsells TI cig-a-likes (easy to use, more nicotine)



Nicotine salt vs freebase

- Freebase: Slower absorption; higher nicotine concentration feels too harsh
- Salt (added benzoic acid): Faster, allows stronger e-liquid, allows lower e-liquid consumption, needs less battery power; but less vapour