

Electronic Cigarettes: Posing New Challenges for Clinicians

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- I undertake research and consultancy for pharma companies that develop and manufacture smoking cessation medications (including GSK, Pfizer, Novartis, J&J).
- I don't do consulting for tobacco companies or e-cig companies.
- Wrote a regular weblog for a health website at:
www.healthline.com/blogs/smoking_cessation/
- Volunteer as a "Health Expert" on the smoking cessation community on
www.WebMD.com
- Thanks to numerous colleagues for sharing their slides.

Objectives

Upon Completion of the program, participants will be able to:

- Describe the various types and components of electronic cigarettes (e-cigarettes)
- Describe the current evidence for the clinical use of e-cigarettes among tobacco users
- Respond to clinical inquiries regarding e-cigarettes from patients and colleagues

“If people have difficulty overcoming both nicotine dependence and long-term habit change, then surely the solution is to help them avoid most of the health risks with only a minimal alteration in their nicotine-seeking habits. This implies a nicotine replacement device which looks like a cigarette and delivers cigarette-like boli of nicotine, but does not deliver the tar and carbon monoxide which cause the vast majority of smoking-related disease..... the development and promotion of such a product (and its eventual replacement of tobacco) could have massive beneficial public health implications lasting into the 21st century.” (Foulds, 1994)

Foulds J. Nicotine replacement therapy does work: time to stop sitting on the fence. A reply. *Addiction* 1994; **89**:438–9.

“There is a fine line between being visionary and being wrong.

Unfortunately you have to be a visionary to see it.”

Dr Sheldon Cooper

The Big Bang Theory

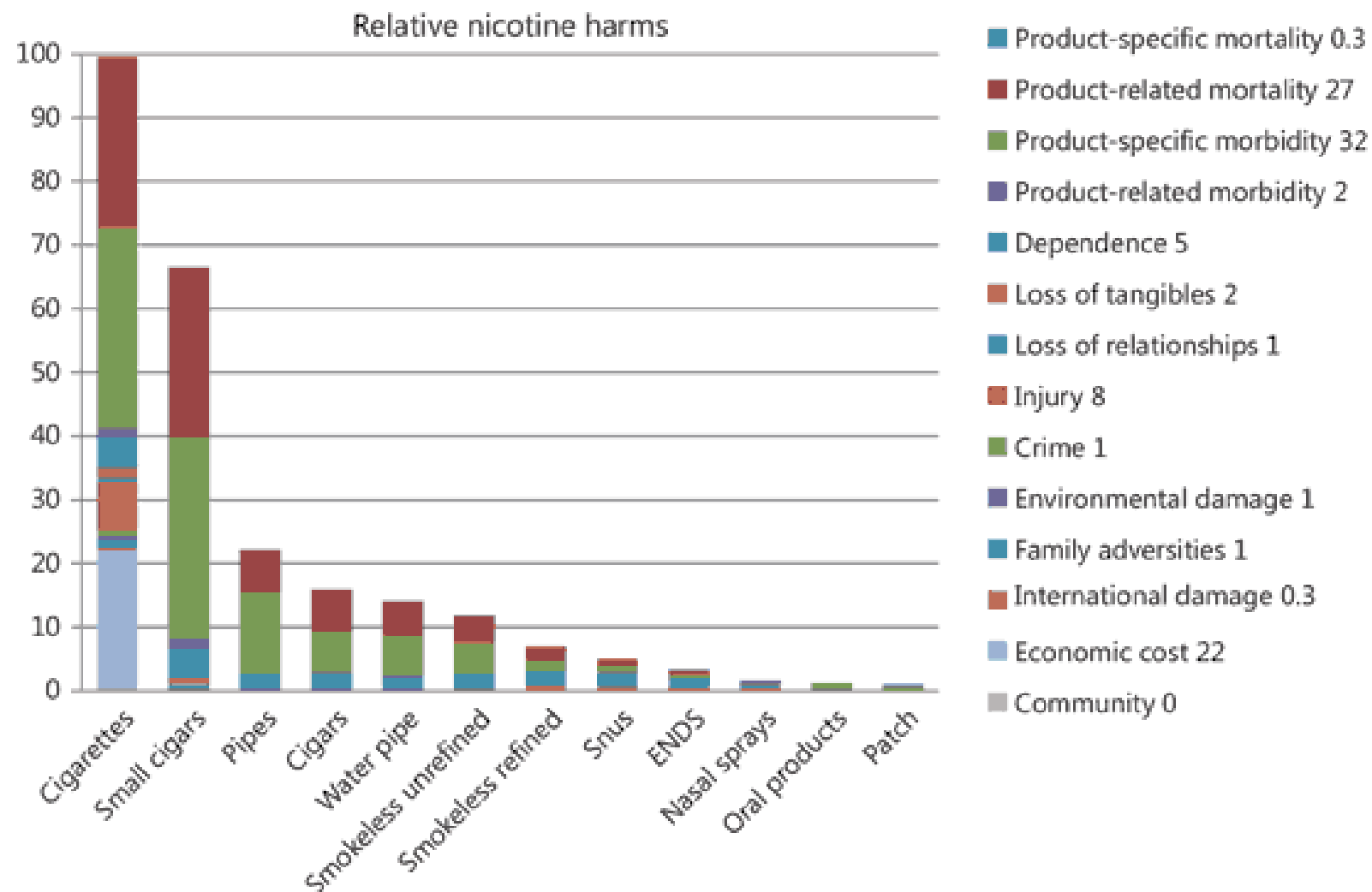


Fig. 2. Overall weighted scores for each of the products. Cigarettes, with an overall harm score of 99.6, are judged to be most harmful, and followed by small cigars at 67. The heights of the colored portions indicate the part scores on each of the criteria. Product-related mortality, the upper dark red sections, are substantial contributors to those two products, and they also contribute moderately to cigars, pipes, water pipes, and smokeless unrefined. The numbers in the legend show the normalized weights on the criteria. Higher weights mean larger differences that matter between most and least harmful products on each criterion.

Nutt DJ, Phillips LD, Balfour D, Curran HV, Dockrell M, Foulds J, Fagerstrom K, Letlape K, Milton A, Polosa R, Ramsey J, Sweanor D. Estimating the harms of nicotine-containing products using the MCDA approach. *European Addiction Research*. 2014 April; 20:218-225 link: <http://www.karger.com/Article/FullText/360220>

There is no such thing as “an e-cig”.
There are many different e-cigs

**1st generation
device**



**2nd generation
device**

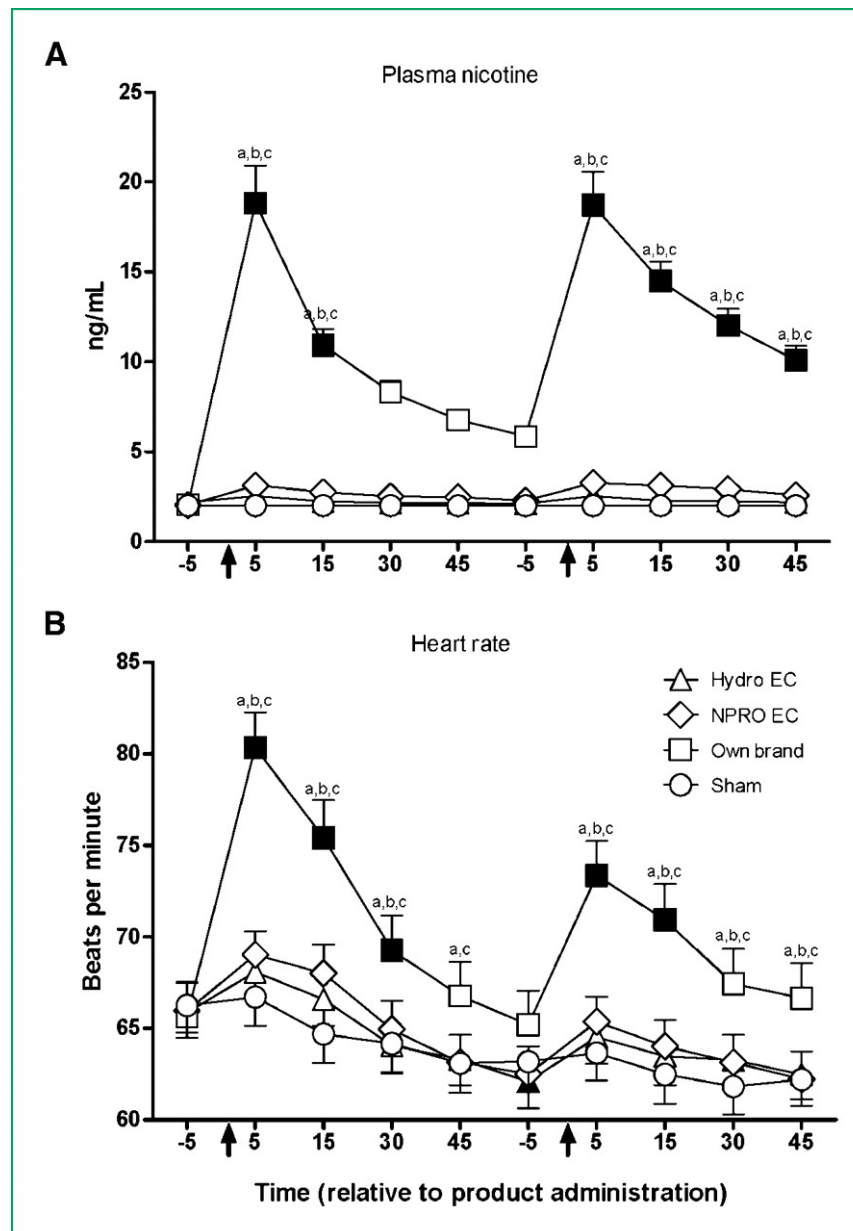


**3rd generation
device**



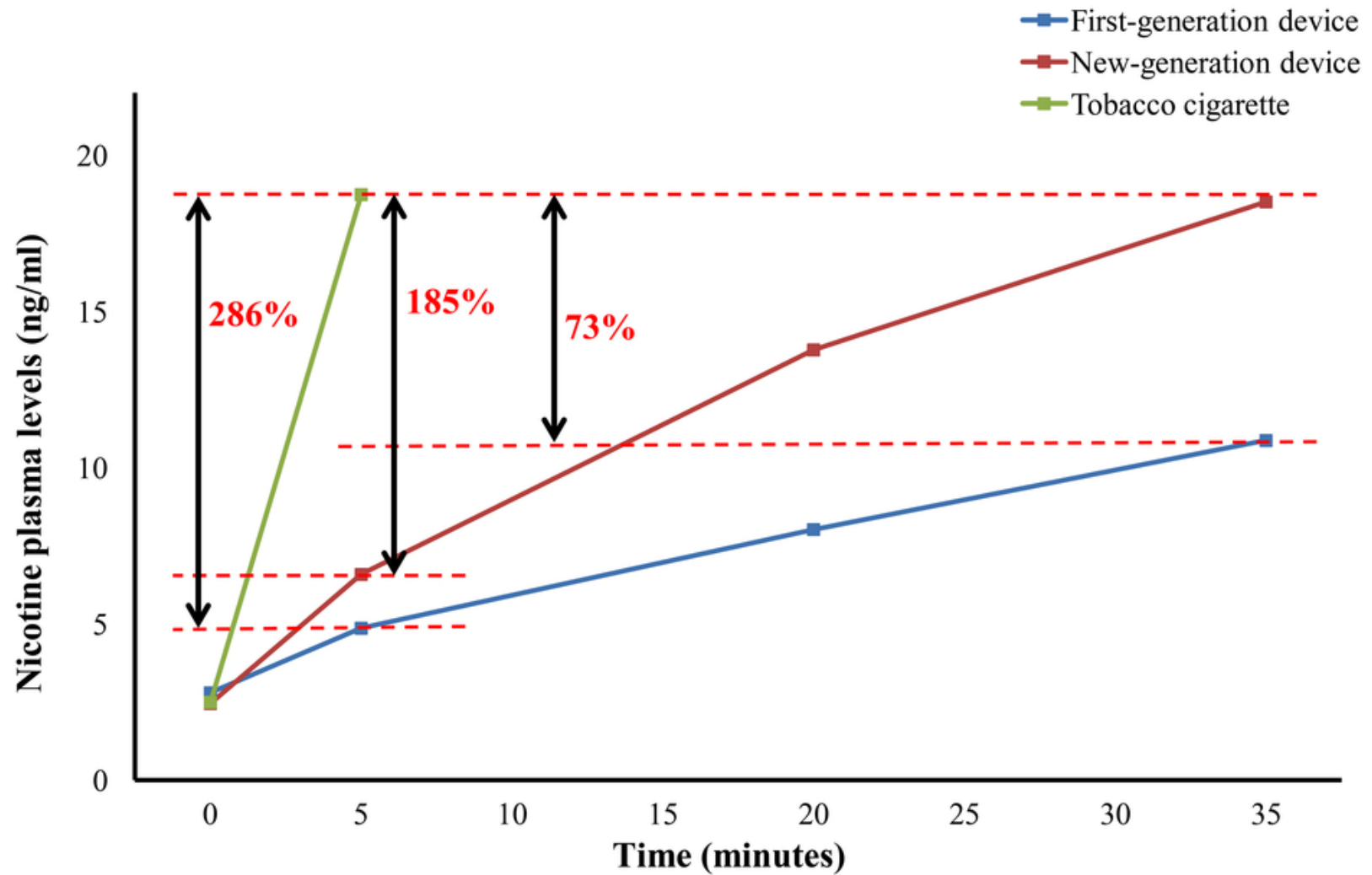
Examples of electronic cigarette devices currently available on the market
(Farsalinos and Polosa, 2014)

Mean data for nicotine blood plasma (A) and heart rate (B) as a function of condition and time.

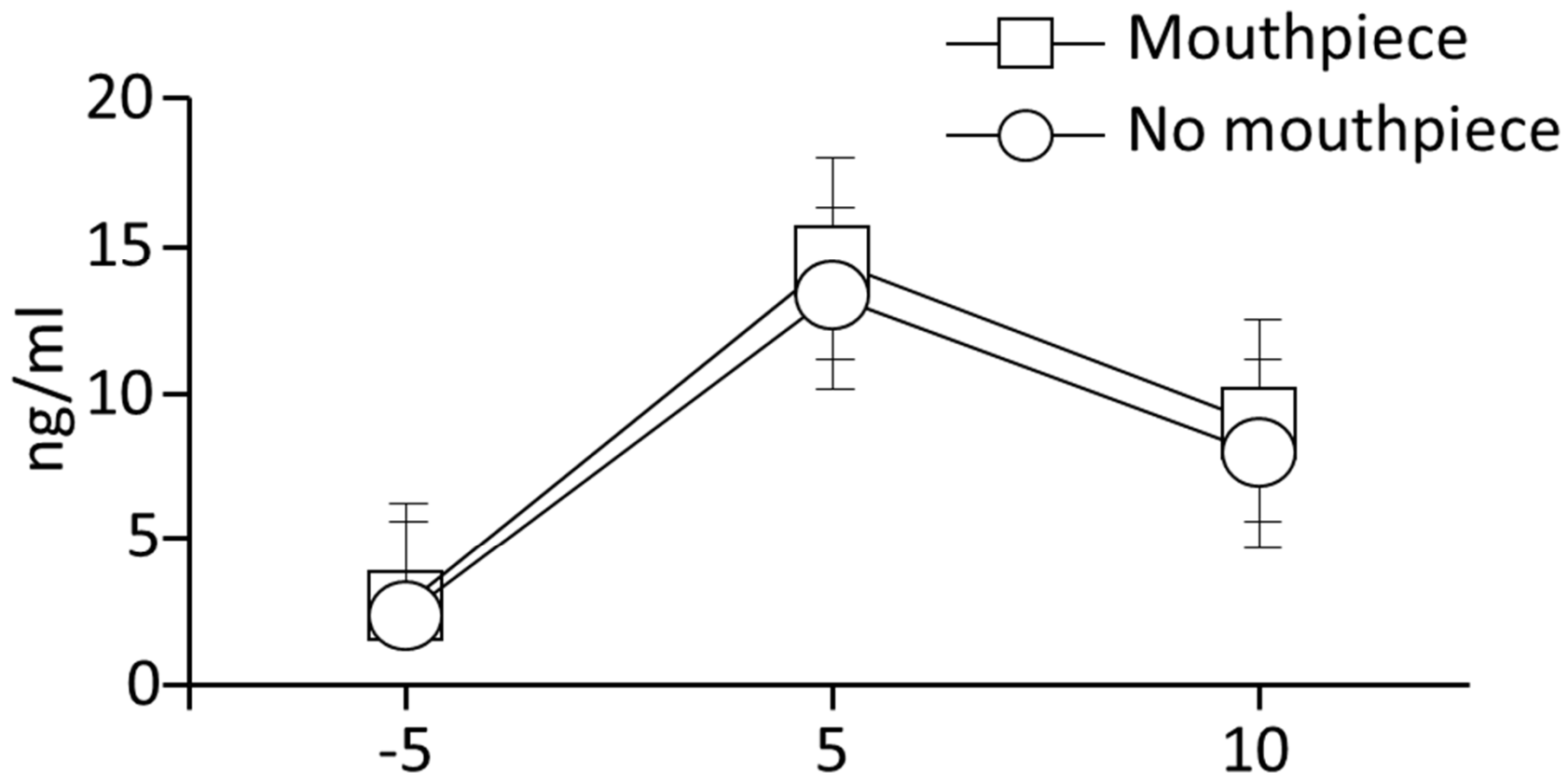


Vansickel A R et al. Cancer Epidemiol Biomarkers Prev 2010;19:1945-1953

Farsilanos et al, 2014, Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices

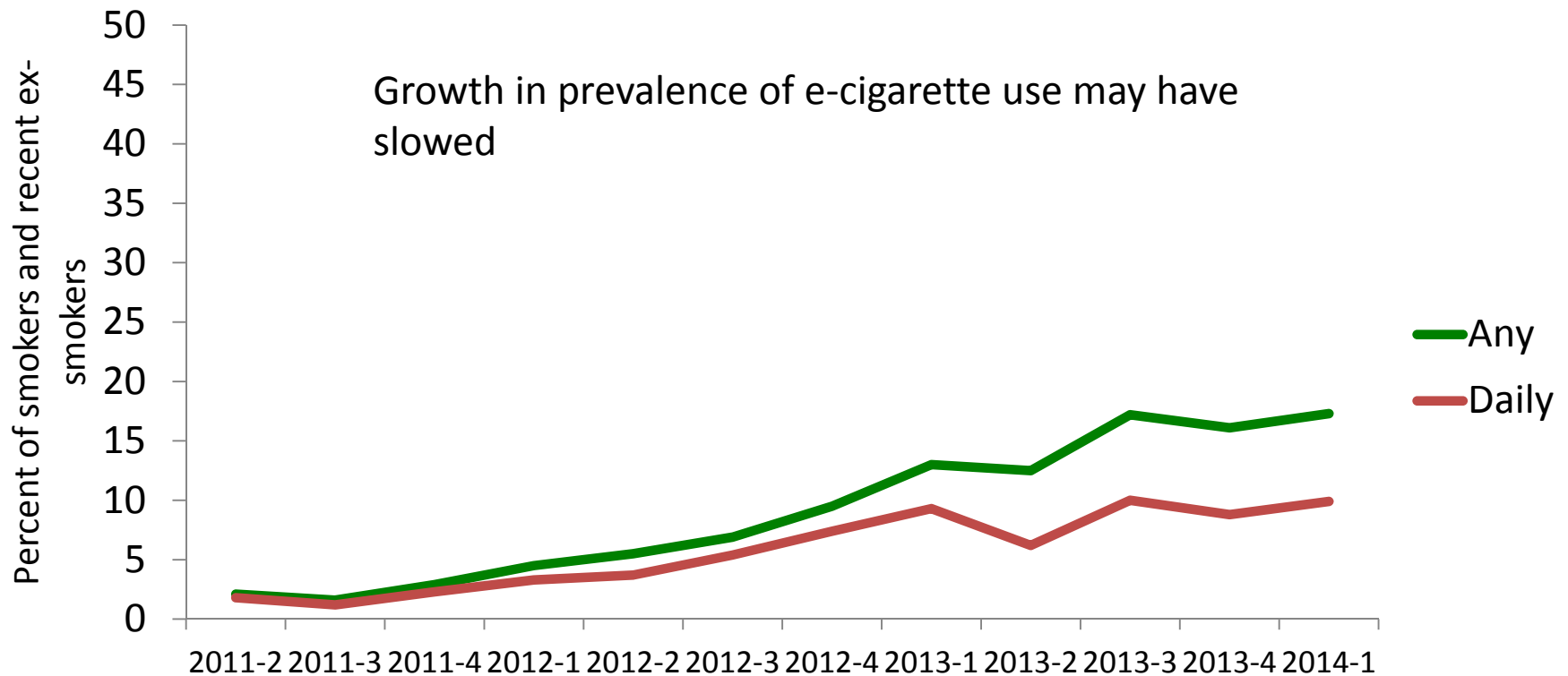


Some e-cigs can produce a boost in blood nicotine levels of >12 ng/ml from 10 puffs in 5 mins. (Spindle, Breland & Eissenberg, SRNT 2014)



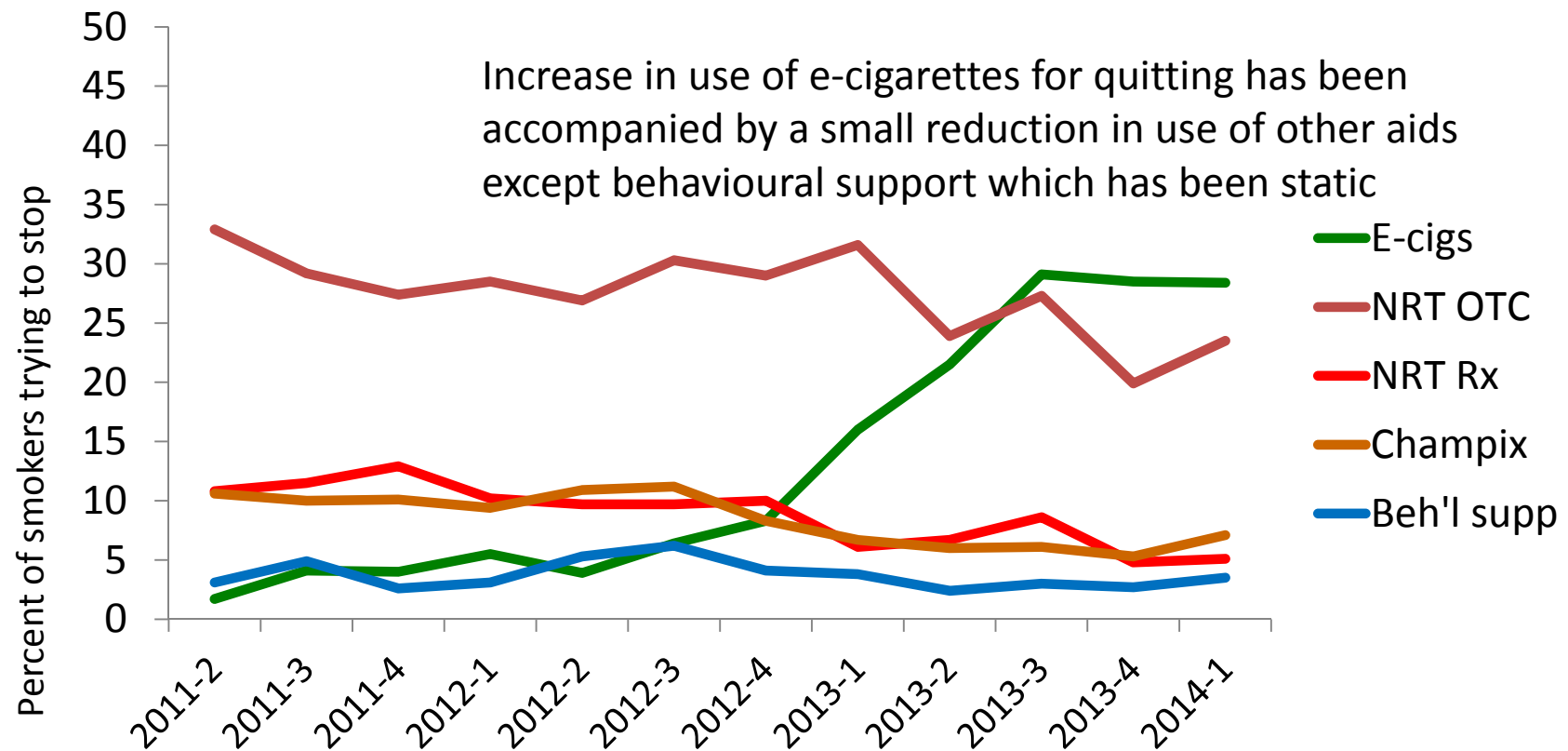
Mean plasma nicotine concentration (+/- SEM) from 5 experienced ECIG users using their preferred device and strength/flavor in two sessions that differed by whether a mouthpiece-based topography system was attached to the ECIG. Nicotine levels increased significantly in each session, independent of mouthpiece condition.

Prevalence of electronic cigarette use: smokers and recent ex-smokers



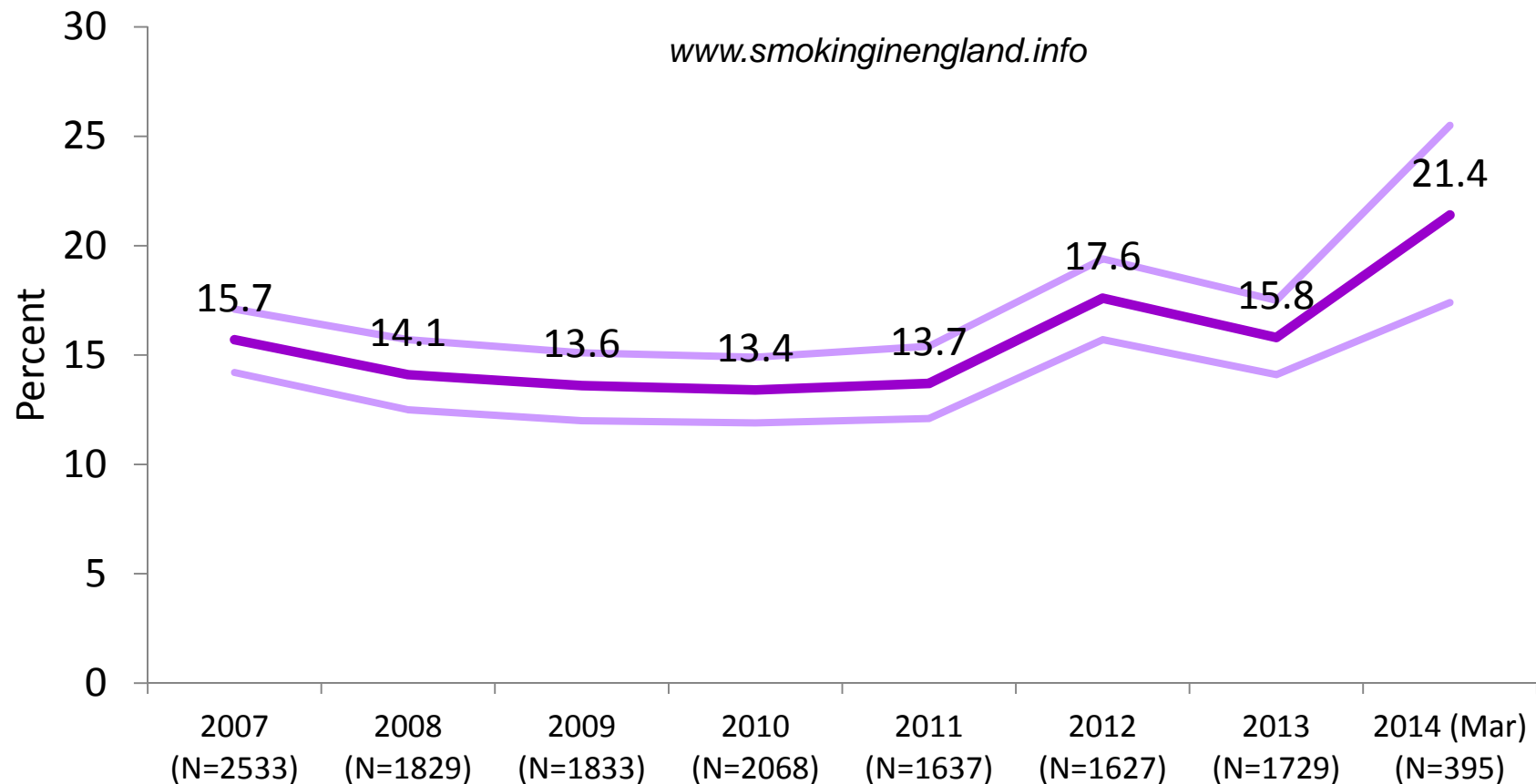
N=11,666 adults who smoke or who stopped in the past year; increase $p < 0.001$

Aids used in most recent quit attempt



N=4,935 adults who smoke and tried to stop or who stopped in the past year

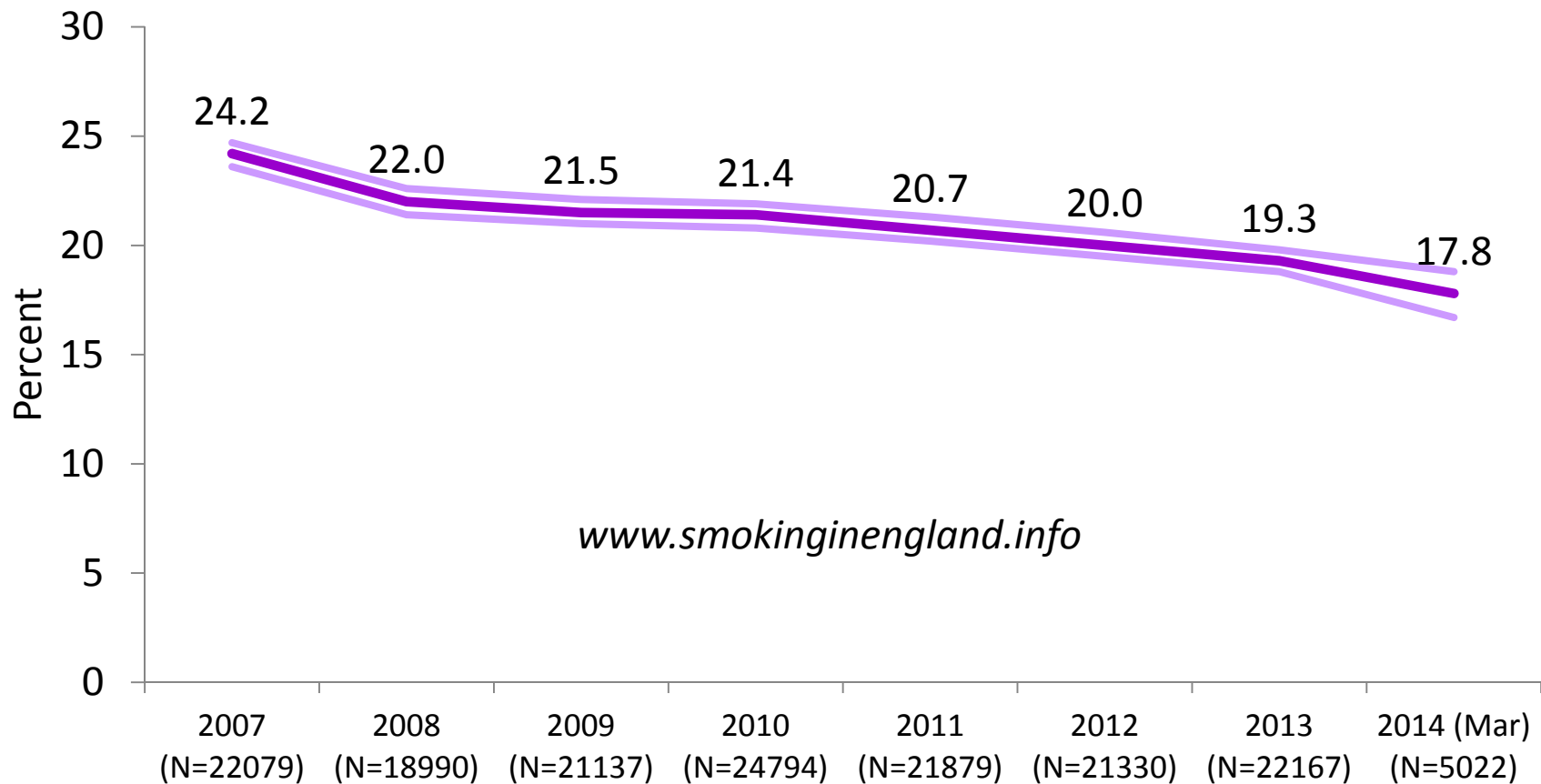
Success rate for stopping in those who tried



Base: Smokers who tried to stop in the past year

Graph shows prevalence estimate and upper and lower 95% confidence intervals

Cigarette smoking prevalence



Base: All adults

Graph shows prevalence estimate and upper and lower 95% confidence intervals

Conclusions

- The increase in electronic cigarette use prevalence continues but may have slowed
- Growth in electronic cigarette use has been accompanied by a reduction, albeit smaller, in use of licensed nicotine products and prescription medication but not use of behavioural support
- Evidence does not support the view that electronic cigarettes are undermining motivation to quit or reduction in smoking prevalence
- Use of e-cigarettes by never smokers remains extremely rare
- Evidence conflicts with the view that electronic cigarettes are undermining tobacco control or 'renormalizing' smoking, and they may be contributing to a reduction in smoking prevalence through increased success at quitting smoking

Conclusions

- Some countries have already banned e-cigs (e.g. Brazil, Australia). Is banning the appropriate response to e-cigs while allowing toxic cigarettes to dominate the nicotine market?
- E-cigs should be regulated so they cannot be sold to under 18s, should have adequate safety standards (e.g. childproof) and quality controls (e.g. no toxicants in e-liquid). E-cigs should not be used in indoor public/workplaces covered by clean indoor air legislation.
- E-cigs can do most good NOT in the clinician's office, but rather by competing effectively in the nicotine marketplace against much more harmful smoked tobacco products (primarily cigarettes).

Clinical Scenario #1 (Foulds)

- “I’m a heavy smoker and both my parents were smokers who died of lung cancer. I’ve tried all the meds but never quit for more than a week. I’ve heard that e-cigarettes can help smokers to quit and I really want to give it a shot. What can you tell me about them?”
- 1. Support Quit Attempt
- 2. Assess motivation and dependence
- 3. Assess prior quit attempts and inform about all treatment/support options
- 4. Inform on what we know and what we don’t know about e-cigs.
- 5. Assist smoker to develop a plan to quit smoking
- 6. Arrange a follow-up

Clinical Scenario #1 (Foulds)

- If patient has only tried NRT monotherapy, inform about (a) combination NRT (b) reduce to quit (c) bupropion and varenicline options.
- Inform about additional support available: 1-800 QUIT-NOW
In New York State, call 1-866-NY-QUITS (1-866-697-8487) or visit nysmokefree.com
www.smokefree.gov www.becomeanex.org
- Inform on what we know and what we don't know about e-cigs.
- Many different types, currently unregulated, no smoke
- Not proven as safe and effective, no clear instruction for use
- Clinical trials to date have had disappointing results but have exclusively used first generation models.

Liquid



Contents

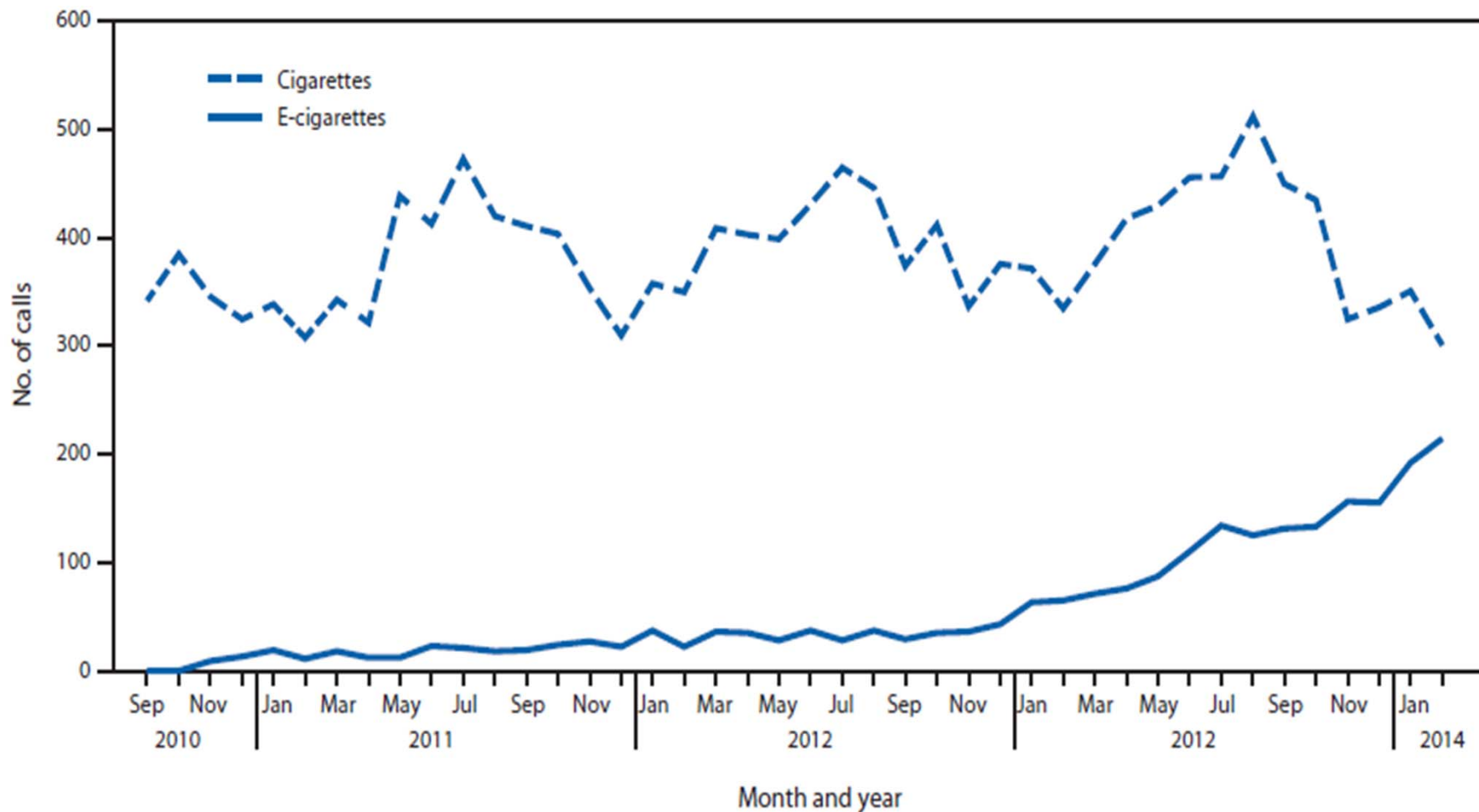
- Propylene glycol and/or Vegetable glycerine (glycerol)
- Nicotine (in mg/ml; ranging from 0-36)
- Flavourings (e.g. tobacco, mint, fruit, menthol etc)
- Additives



Clinical Scenario #1 (Foulds)

- “The evidence from clinical trials suggests that the best quit rates are achieved by maximizing your psychosocial support (e.g. group face-to-face support plus quitline plus online) and pharmacological support (e.g. combination NRT or varenicline for as long as it takes). If you choose to use these treatments they will likely increase your chances of quitting by 2 to 4 times”
- An e-cigarette may help, but we don’t yet have very solid data on how helpful they are or what the longer term health risks may be.
- If you choose one that provides you with a decent amount of nicotine it is likely it will help you in much the same way as NRT. As the e-cig delivers nicotine plus a few more chemicals it is very likely to be much less harmful than smoking.

Number of calls to poison centers for cigarette or e-cigarette exposures, by month – USA, Sept 2010 to Feb 2014



Clinical Scenario #3 (Foulds)

- 52 year-old woman, smoked a pack a day, had more than 7 quit attempts over past 10 years. Some success with meds (NRT or Varenicline) and counseling, but always relapsed between 2 and 6 months after the initial quit date. She returns for an annual follow-up, and this time is 9 months tobacco free (exhaled CO=1ppm, FEV1 improved significantly compared with smoking baseline), ever since started using an e-cig on a daily basis....initially a disposable from a gas station, then a rechargeable cigalike, then an “Ego Tank” with a button, and now she is in love with some fancy e-cig called a “Provari” that she found online. I asked her to complete the Penn State Electronic Cigarette Dependence Index, and she obtained a very high score (15/20), only a couple of points lower than she obtained on the PS Cigarette Dependence Index at initial assessment. She feels the e-cig has really helped her stay off cigarettes and has no plans to quit, but asks about the long term health effects.

Penn State Electronic Cigarette Index

1. How many times per day do you usually use your electronic cigarette?
(assume one “time” consists of around 15 puffs, or lasts around 10 minutes)

___30___ times per day (5)

2. On days that you can use your electronic cigarette freely, how soon after you wake up do you first use your electronic cigarette?

___20___ minutes (3)

3. Do you sometimes awaken at night to use your electronic cigarette? Yesx No (1)

4. If yes, how many nights per week do you typically awaken to use your electronic cigarette? ___3___ nights (2)

5. Do you use an electronic cigarette now because it is really hard to quit? Yes Nox (0)

Penn State Electronic Cigarette Index

6. Do you ever have strong cravings to use an electronic cigarette? xYes No (1)

**7. Over the past week, how strong have the urges to use an electronic cigarette been?
(check one)**

No urges Slight Moderate xStrong Very strong Extremely strong (1)

8. Is it hard to keep from using an electronic cigarette in places where you are not supposed to? Yes NoX

When you haven't used an electronic cigarette for a while... OR when you tried to stop using...

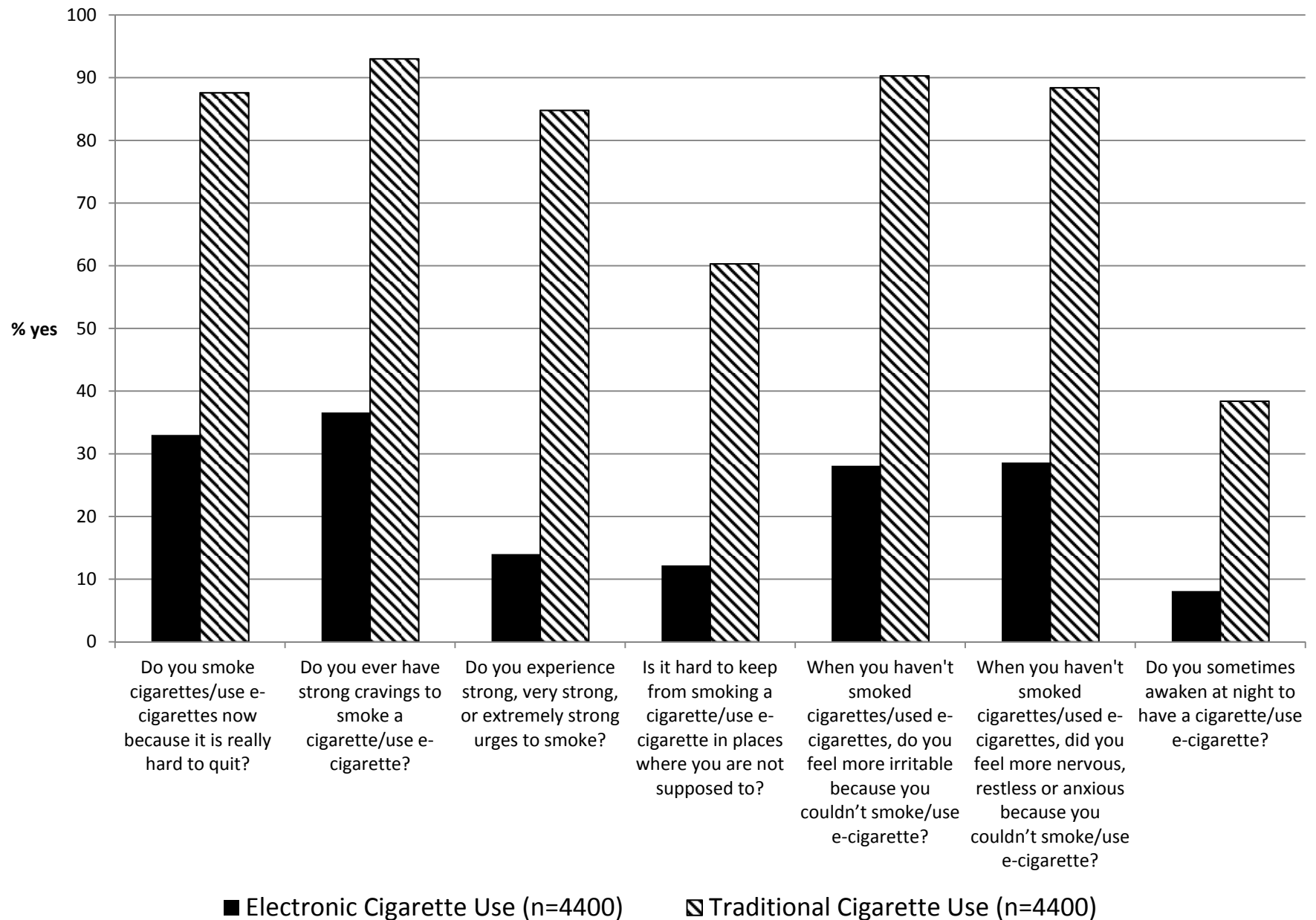
9. Did you feel more irritable because you couldn't use an electronic cigarette?
 xYes No (1)

10. Did you feel nervous, restless or anxious because you couldn't use an electronic cigarette?

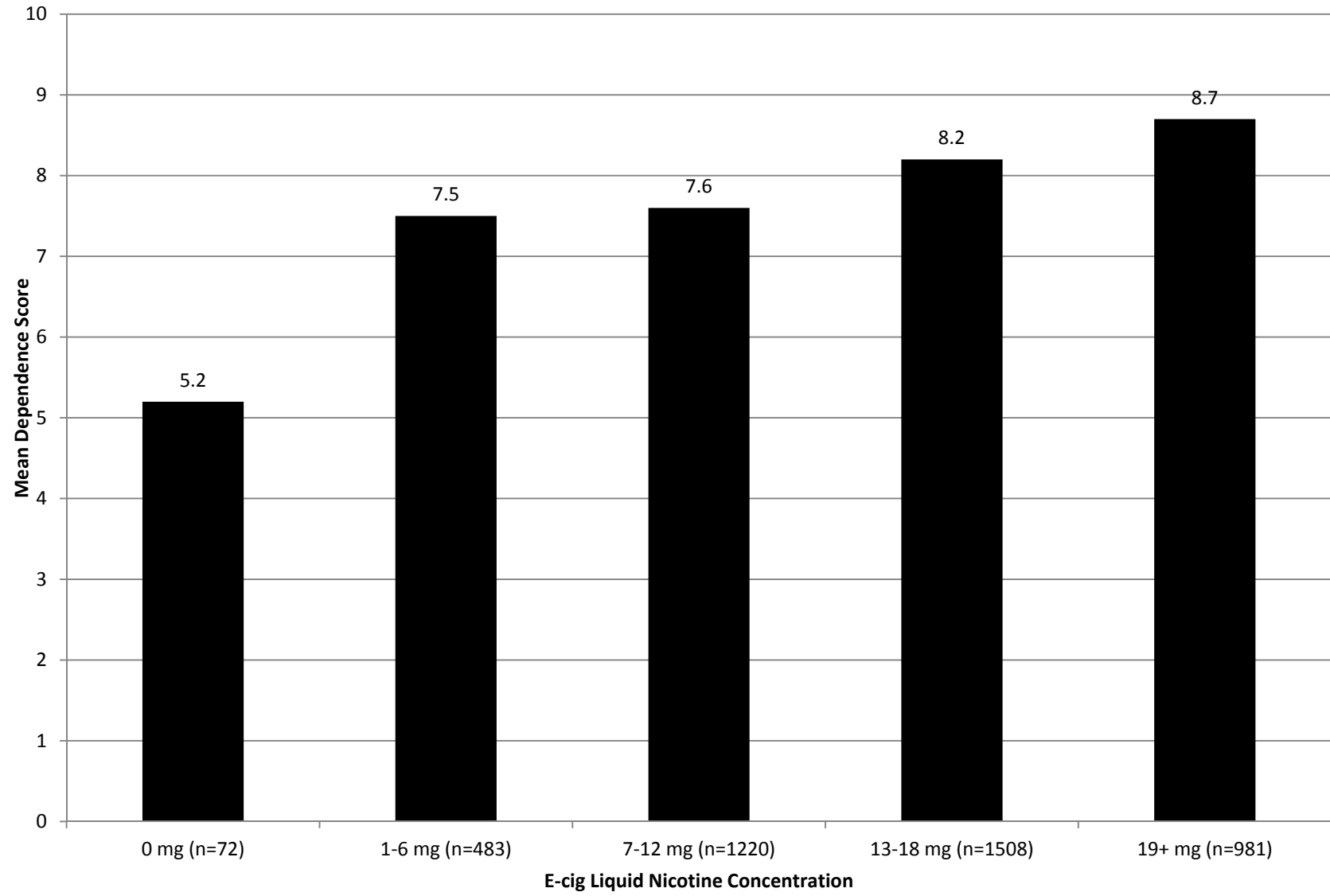
x Yes No (1)

11. What concentration of nicotine is in the liquid you typically use with your e-cig?
18 mg/ml.

Penn State Nicotine Dependence Questions



Penn State Electronic Cigarette Nicotine Dependence Index by e-cig nicotine concentration* (n=4264)



* all between group p-values <0.02 except between 1-6 mg and 7-12mg groups

Clinical Scenario #3 (Foulds)

- The long term health effects of inhaling nicotine, propylene glycol, vegetable glycerin, flavorings and other unknown additives are unknown
- They are very likely worse for health than inhaling fresh air
- They are very likely much less harmful to health than smoking cigarettes.
- The most important thing for this patient is to stay off cigarettes in the immediate future
- Encourage to start thinking about weaning herself off the e-cigs, possibly by gradually reducing the nicotine concentration in her liquid....but only if she feels secure in not relapsing back to smoking

Conclusions

- The Food & Drug Administration recently announced its intent to regulate electronic cigarettes
- However it will likely be years before these products are under full regulatory control, and even then our knowledge about their safety and efficacy will likely remain unclear.
- They are very likely much less harmful to health than smoking any tobacco product (but note individual issues, e.g. pregnancy).
- We should discourage all non tobacco users from initiating e-cig use
- We should encourage all dual users to switch completely to e-cigs
- We should preserve the right to breath clean air in the workplace (as opposed to air that is less toxic than cigarette smoke)
- However, we should be honest with the public about what we know and don't know about e-cigs, without demonizing them. Our focus should be on reducing use of smoked products.

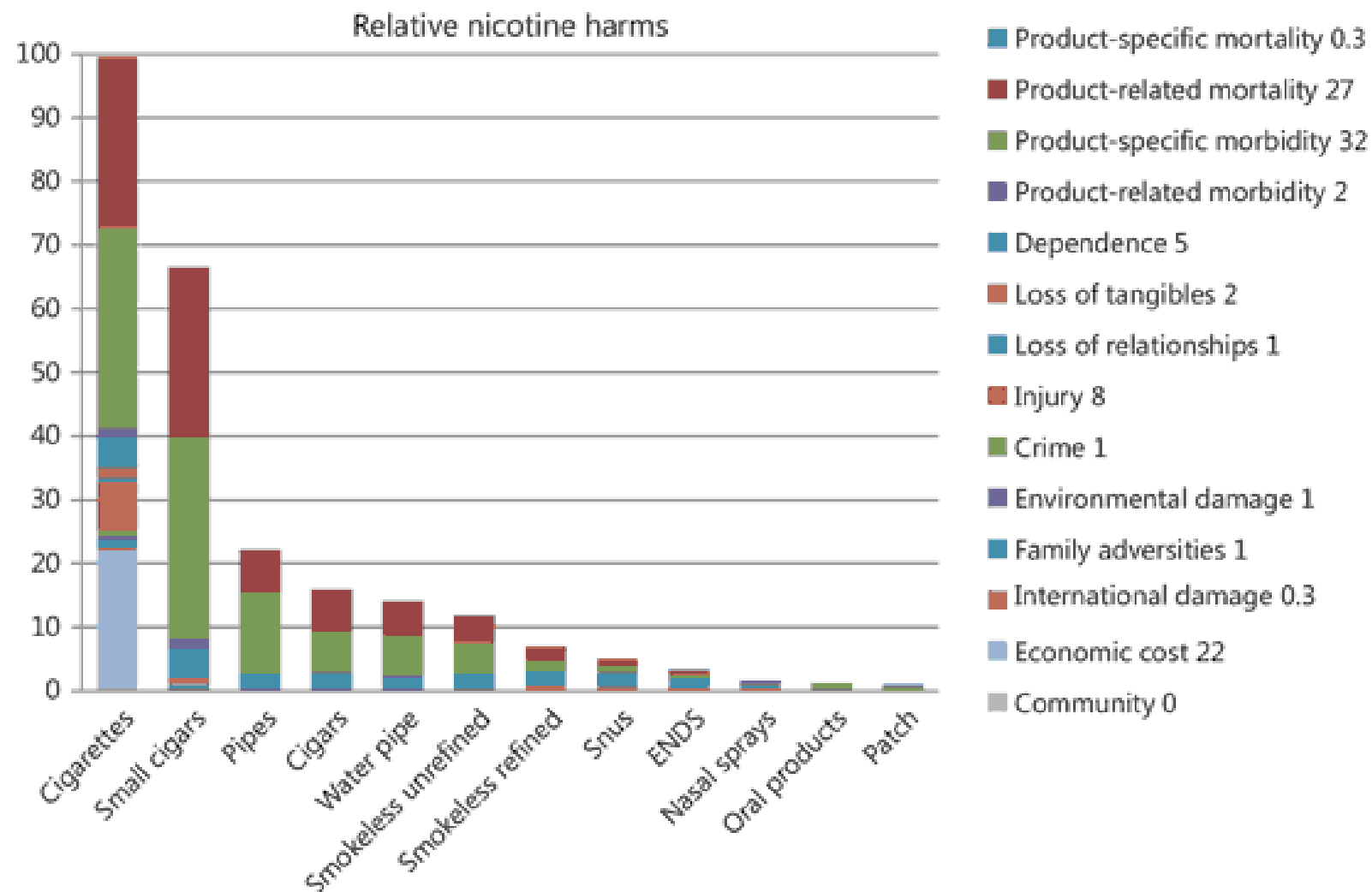


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