More heat than light – new US statistics on youth vaping provide no basis for FDA policy

written by Clive Bates | 25 November 2018



What's going on in their lives?

New data on youth vaping. Time to take a closer look at the disclosure of *some* 2018 U.S. National Youth Tobacco Survey data (see MMWR). The survey is conducted annually, with field work in February-June. Usually, the results are published in headline form about a year later (2017 data was published in June 2018) and full datasets some time after that. 2018 is different however. CDC and FDA (the co-authors) have rushed out data that they argue supports the claim there is an 'epidemic' of teenage vaping use (see FDA chief calls youth e-cigarette an 'epidemic', Washington Post).

FDA action in response. In response to the alarm that it has done much to create, FDA has now taken a variety of actions, notably to restrict access to e-cigarette flavours that are not tobacco, menthol or mint – as described in a 15 November statement by Scott Gottlieb, FDA Commissioner.

Backing for the action? But does the data support any of this regulator activity? I conclude that the partial release of data does not provide justification for FDA's policy. This is because the data required to understand underlying changes in the

pattern of tobacco use has been withheld. In other words, the data to create alarm has been released, but the data required to understand if the alarm is justified and the policy is sound has not been released.

Six new data points

For high school students, the MMWR authors provide just six new data points for 2018. Similar data are presented for middle school, but these are not discussed here because high school data really drives the politics. High school students are 14-18 years old (9th-12th grade). Here are the six new data points that have been disclosed.

1. E-cig past-30 day use is **20.8%**, 3.05 million, up by 78% from 11.7% in 2017.
2. Any tobacco product past-30 day use is **27.1%**, 4.04 million, up from 19.6% in 2017. This includes e-cig use in the definition of 'tobacco product' and whether or not it is nicotine-based.
3. Regular e-cig use: use on ≥20 of the past 30 days increased from 20.0% (346,000) 2017 to **27.7%** (845,000) in 2018 of e-cig users. This is the fraction of the e-cig user population that are regular users, not a fraction the student population overall.
4. Current use of any flavoured e-cigarettes increased among current e-cigarette users (from 60.9% in 2017 to **67.8%** in 2018). I am assuming that tobacco flavour doesn't count as 'flavoured' and therefore that exclusive use of tobacco flavour accounts for the balance (100%-67.8% = 32.2%), as there are NO widely available unflavoured e-cigarettes. It is unclear where cannabis vapes fit. I should not have to do this if the data was properly reported.
5. Current use of menthol- or mint-flavoured e-cigarettes increased among all current e-cigarette users from 42.3% to **51.2%**
6. Current use of menthol- or mint-flavoured e-cigarettes among current exclusive e-cigarette users from 21.4% to **38.1%**

What to make of the new data?

I have tried to figure out what conclusions can and, more usually, cannot be drawn from the data disclosed. What would an objective, evidence-based policy-

maker make of this? She would not be impressed.

1. 'Any combustible use' is the critical indicator of risk but it is not disclosed

The key public health indicator should surely be prevalence the most harmful behaviour: i.e. "combustible tobacco use" (or even *regular* combustible tobacco use). This is not reported at all and I can see no way to infer it from what is reported. But this quantity is absolutely critical to interpreting what is going on here. If there had been a fall in combustible product use, then it may point to substitution of smoking by vaping. If level, there may also be more dual use, which may eventually prove beneficial. Or an increase, which would be alarming if sustained.

For a more complete discussion of the interactions between smoking and vaping, and the possible harms that could arise from ill-conceived intervention, please see letters from Iowa Attorney General, Thomas Miller and others: Youth tobacco and nicotine use – proportionate and responsible reaction (November 2018) and Regulation of Flavors in Tobacco Products (July 2018).

CDC/FDA have not published the most important public health indicator for youth tobacco use. Why?

2. Frequency distribution of e-cig use not properly disclosed and does not help characterise different types of use

The standard measure of *current use* is 'any use on one or more days in the past 30 days'. But on how many days matters a great deal – we are interested in the frequency or intensity of use. It is essential to understand the frequency of use in order to characterise the extent to which the behaviour is experimental/frivolous or an established habit (e.g. daily or most days) and therefore more of a reason for concern and possible policy focus. Policymakers should be focussed primarily on the more intensive users – and among these users, remaining aware that vaping may be beneficial if they are also smokers.

FDA/CDC have not reported the full frequency distribution for e-cig use (only the single ≥20 days figure) and not the more important daily use (indicating possible dependence). Why not the whole distribution in the way normally reported and

disaggregated as follows?

- 1-2 days
- 3-5 days
- 6-9 days
- 10-19 days
- 20-29 days
- All 30 days (daily)

Instead of providing the full frequency distribution as above, they have merged the last two and not provided any of the rest. If they are confident in the increased share of ≥ 20 days use in 30 (27.7%), they must have the full distribution – why not a neat little table to give the full picture? How hard can it be? ***The missing data may reveal how much of the so-called 'epidemic' is basically trivial use.***

3. Smoking and tobacco use status of frequent e-cig users really matters but remains undisclosed

Regular e-cig use on ≥20 of the past 30 days increased from 20.0% (346,000) 2017 to **27.7%** (845,000) in 2018 of e-cig users – this might imply a shift in the frequency distribution towards more frequent use – though because we do not know what happens at the low frequency end of the distribution, it may represent a polarisation.

The rise in frequent (≥ 20 days) e-cig users is quite sharp: from 346,000 (2.3% students) to 845,000 (5.8%). But what if the increase among the more frequent e-cig users *is concentrated among smokers?* What if this growth represents a move of teenage nicotine use from smoking to vaping, or from exclusive smoking to mixed smoking and vaping? One of the most vital missing pieces of the picture here is the tobacco use characteristics of the more frequent e-cigarette users – and therefore whether we are witnessing is a youth harm-reduction effect. We know that in previous years, regular vaping has been concentrated among smokers and ex-smokers – something that is reassuring and may even be positive.

This gap in the data provided is so crucial it could be the difference between these results being good news and bad news, and a policy intervention being justified or actively harmful.

4. Flavor use among adolescents – appears to be dominated by the flavours NOT targeted by FDA.

The flavours data (4,5,6 above) is difficult to interpret because people can use mint, menthol, tobacco, fruit and many different flavours all in the course of a month – i.e. use of each category is not exclusive. It is also difficult to interpret because FDA/CDC use terminology disconnected from reality – almost ALL e-cigarettes are flavoured with flavouring agents of some kind. Even though FDA insists on calling e-cigarettes 'tobacco products' there is no tobacco flavour coming from the nicotine – it is added as a flavour like any other. I have just assumed that when the survey reports 67.8% use flavours they mean the rest use tobacco flavour. This is annoying and unnecessarily confusing.

But we can say this… if exclusive non-flavour (i.e. tobacco flavour) use accounts for 32.2% and mint/menthol another 51.2%, then at least* 83.4% are using the mint/menthol/tobacco flavour in the course of a month. So more than four out of five adolescent e-cigarette users are using tobacco, menthol or mint in the course of 30 days.

Yet, bizarrely, it is the *other flavours* (fruit, candy etc) that have attracted FDA's regulatory iron fist. Mint/menthol and tobacco can continue to be sold in convenience stores (along with cigarettes). However, the targeted flavours are *anything but* tobacco, menthol and mint – and these must only be sold in age-restricted, in-person locations or with enhanced age-verification – see FDA statement, 15 Nov). Yet, the non-targeted flavours are used by more than 80% of users. ***There is no connection between the policy and the data, which demonstrates substantial use of the flavours that are not subject to FDA intervention***.

We cannot even tell how much use there is of the targeted flavours. CDC/FDA has not provided the data on prevalence of use of flavours that are the subject of the main policy intervention: i.e. anything but tobacco, menthol and mint. We can only infer that use of these FDA-targeted flavours is in a range from a minimum of 16.6% (the difference between any flavour use and menthol/mint use – assuming mint/menthol users *never* used other flavours) and a maximum of 67.8% (if all mint/menthol users also *always* used other flavours). Because this range is so large, we are basically in the dark about the prevalence of use of the flavours that are targeted by the FDA policy. CDC/FDA have not provided appropriate data to

support FDA policy. ***FDA/CDC have not provided any meaningful data on the flavours that are the subject of FDA's intervention***.

* Why do I say 'at least'? More may be using tobacco flavour alongside non-mint/menthol flavour.

5. Flavour preferences of dual users

CDC/FDA say that among *exclusive* e-cigarette users, 38.1% use menthol/mint – and this compares to a higher fraction of 51.2% among *all* e-cig users, including those using other tobacco products as well. They do not disclose what proportion of e-cigarette users are exclusive, so the statistic is of limited value. However, it does mean that those using other tobacco products as well as vaping are more likely to be using menthol/mint – perhaps these are menthol cigarette users or they like the idea of clearing their smokers' breath with mint. I don't really know why this statistic earned a place in the MMWR, when many others of greater value didn't make the cut. ***Why report data without the obvious additional data necessary to interpret them?***

6. Type of vape – no nicotine, nicotine or cannabinoids?

No data is provided on whether these users are using non-nicotine e-liquids, nicotine, or cannabinoid liquids. Given the 2017 Youth Risk Behavior Surveillance reporting found 19.8% high school students using cannabis in the past 30 days, a substantial uptake of vaping as the preferred means of administering cannabis would potentially confound and complicate what are supposed to be tobacco-use data. ***What is reported as 'tobacco use' may not even be nicotine use – and cannabis vaping greatly complicates the picture.***

7.Tobacco-use without use of e-cigarettes is reducing

On overall prevalence they provide e-cigarette use (exclusive, dual-use, poly-use all included but not disaggregated) and total tobacco product use (i.e. any for of consumer nicotine use including e-cigarette use, but not disaggregated). The only data we can infer from this is the change in tobacco users not using e-cigarettes: that fell 230,000 from 1,220,000 to 990,000 or by 19% between 2017 and 2018. The prevalence of non-e-cig tobacco users fell from 7.9% to 6.3% and the proportion of all tobacco users now using or a safer form of nicotine

administration (i.e. e-cigs) rose from 59.7% to 76.8%. (Note: I am following FDA convention of describing e-cigs as tobacco products).

This is interesting because it shows a he extent to which e-cigs are a now major part of teen tobacco use. Of all tobacco/nicotine users – over three quarters (76.8%) have used an e-cig in the last 30 days. ***I actually see hope not alarm in that number: the advance of creative destruction and beginning of the end for cigarettes. Vaping may be driving out smoking.***

Clarification: in this blog 'non-e-cig tobacco users' refers to the youth who use some sort of tobacco product but do not use e-cigs. This is not the same as the proportion of youth who use tobacco products other than e-cigs – as that quantity includes those who also use e-cigs (i.e. dual- or poly-users). This quantity is of substantial interest but cannot be inferred from the data disclosed.

8. Why does it take so long to get the NYTS data out?

Fieldwork for NYTS in 2017 was done from 13 Feb-14 Jun 2017, and I assume 2018 would be similar. Surely CDC can get the most relevant data into the public domain in less than five months from completing the survey? The last Eurobarometer 458 survey (PDF) (28 countries, 21 languages) did field work in March 2017 and had the main report out by May 2017. ***If FDA is going to respond in real time to an emerging phenomenon it needs to do this with timely data giving a full picture.***

9. Reconciliation with other data

Earlier in November, Vallone et al* published data on youth ENDS use** from the large regular survey undertaken by the Truth Initiative. The study sample is drawn from the Truth Longitudinal Cohort (TLC), a national, probability-based sample of around 14,000 – covering ages 15-34. The survey was conducted February to May 2018 – almost wholly overlapping with the NYTS field work. The age range in slightly different – the Truth survey reports 15-17 year olds but the NYTS uses 'high school' (14-18 years).

Table 1 Weighted demographic characteristics of study sample, and prevalence of ever and current JUUL, ENDS and combustible tobacco use, by demographic and psychosocial characteristics (n=13 357)

	Total sample	Ever JUUL users†	Sig.	Current JUUL users‡	Sig.	Current ENDS users§	Sig.	Current combustible tobacco users¶	Sig.
Overall		6%		3%		10%		17%	
Age (%)			***		***		***		***
15–17 years	17	10		6		11		7	
18–21 years	19	11		8		16		17	
22–24 years	16	5		3		12		18	
25–34 years	48	3		1		7		19	

For NYTS 2018 – high school past 30 day e-cigarette use is **20.8%**, but in the Truth survey, ENDS use** was just **11%** (see table above). This is a very substantial difference and demands an explanation – and I have yet to hear one. But that I doubt that the difference in age range would be sufficient to account for it.

What explains the pronounced difference between the Truth data and CDC/FDA data collected at about the same time.

* Vallone DM, Bennett M, Xiao H, Pitzer L, Hair EC. Prevalence and correlates of JUUL use among a national sample of youth and young adults. Tob Control; 2018 Oct 29 [link]

**Current ENDS use defined as use of one or more of the following products in the past 30 days: e-cigarette, e-cigar, e-hookah, vape pipe, vape pen and hookah pen.

10. In conclusion – more data and rigour is necessary to support FDA's policy interventions

While there is some urgency to understand an emerging phenomenon, this is not a reason for releasing excessively limited and selective data about it. Quite the contrary – the concern creates an imperative to fully understand what is going on, and therefore demands release of as much data as possible as early as possible. The general problem is well stated by Villanti et al. Frequency of youth e-cigarette and tobacco use patterns in the U.S.: Measurement precision is critical to inform public health. *Nicotine Tob Res*. December 2016 [link]

> *Our study highlights the complexity of tobacco use patterns and dominance of poly-use in US middle and high school students. Future studies addressing the full public health impact of movement into or out of combustible tobacco use*

> *will require longitudinal data with appropriate measures of tobacco and e-cigarette product-specific use (eg, frequency and intensity), as well as adequate sample size and a sufficient number of waves to determine how use of individual products, like little cigars, e-cigarettes, and other innovations in emerging alternative nicotine delivery systems, impact progression into or out of more stable patterns of tobacco use.*

And these authors provide clear guidance on reporting tobacco and nicotine use to address these challenges:

> *Currently, most surveillance studies that have reported on national data in the United States do not typically or completely:*
>
> 1. *account for the substantial differences in prevalence by frequency of use;*
> 2. *report on all possible patterns of concurrent poly-use;*
> 3. *characterize patterns in the context of historical (ever) use of both tobacco products and e-cigarette products compared to one another and to never users of any products; or*
> 4. *present metrics for total combustible product use, total tobacco use (excluding e-cigarettes) and total tobacco and e-cigarette use*

None of this wise advice has been followed in the release by CDC/FDA.

As a minimum, FDA/CDC should release the following without further delay:

1. Full frequency distribution for e-cigarette use -including daily use
2. Trend in combustible tobacco use
3. Smoking / and tobacco use status of e-cigarette users – especially regular and daily users
4. Clear information on flavour use, covering tobacco, menthol/mint, and other flavours – recognising that users may try several flavours in a month
5. Use of nicotine-free liquids, nicotine or other psychoactive substances in e-cigarettes if this data is collected

FDA/CDC appear to have chosen exactly and only the data needed to promote their the ‘epidemic’ narrative. At the same time, they have withheld any data that might be used to question it or interpret it with more subtlety. Americans have

been let down by this approach to data and evidence-based policy-making.

Will FDA.CDC take these modest steps towards more complete (less partial and selective) disclosure with an MMWR supplement?

Data summarised

Access Google Sheets spreadsheet here.

Full citation of source

Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018. MMWR *Morb Mortal Wkly Rep* 2018;67:1276–1277 [link]

Other sources

- The US media is losing its mind over vaping and Juul – the questions a credible journalist should ask – my blog
- Youth vaping and the dangers of over-reaction – a letter to the FDA – Attorney General Miller et al
- FDA will ban most vape flavors except in adult-only stores – Vaping 360