THE IMPORTANCE OF ASSESSING PUFFING TOPOGRAPHY TO INFORM E-CIGARETTE EMISSIONS TESTING

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Why Test E-cigarette Emissions?

Measure the output of an electronic cigarette

- Emissions constituents
- Aerosol Mass / consistency

Why?

- Academic research
- Regulatory requirements
- Product development
- Product stewardship/quality

Informing Consumer Exposure

(Either directly or Indirectly)

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What do Regulators Ask For?

Who?	What Emissions?	What Test Conditions?	What Limits?
EU TPD	*"emissions resulting from the use of the product"* (some listed in country-specific guidance)	*"normal or reasonably foreseeable conditions"*	*"a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product"*
US PMTA	*"HPHCs and other toxicants"* (33 listed + other)	*"Intense and non-intense"*	*"Appropriate for the protection of public health"*
UK MAA	"vaporisation products" "thermal decomposition" "metallic and other particles"	*ISO 20768**	*Covered in Non-Clinical section (toxicology) under "normal operating conditions"*

** Specifically for consistency of dose*

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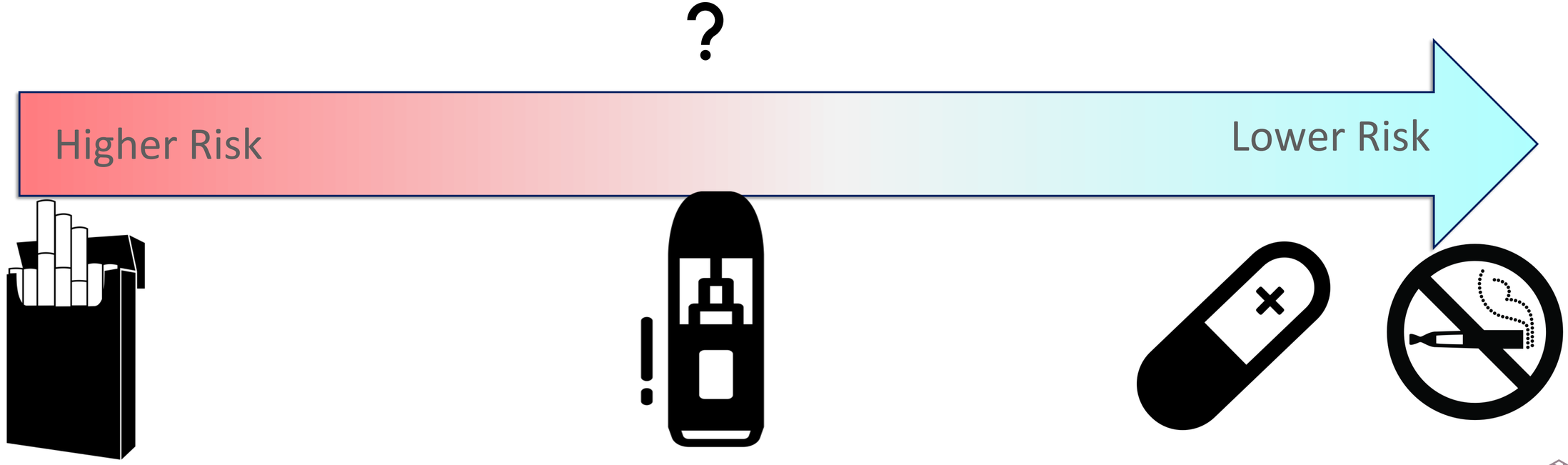
No Limits? How Can We Justify / Assess the Emissions Generated?

What does that mean? (context)

- Comparison to alternative products
- Comparison to literature toxicology data (toxicological risk assessment)



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How Can We Compare Like for Like?

- We can use exposure models to compare across categories
- How much of each emission is a user exposed to for the product/comparator over a set period of time?
- How are consumers using the product? Puffing Topography
  - Puff volume
  - Puff length
  - Puff frequency
  - Puff shape
  - Puffs per day
  - mL of e-liquid used per day

This should be reflected in the parameters we use when testing

"Topography data are needed to understand baseline characteristics pertaining to electronic cigarette use"
- SCHEER Opinion on Electronic Cigarettes: Exposure Assessment, European Commission (2021)

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Standard Puffing Regimes

BENEFITS

Gives guidance on acceptable method

Useful for consistent comparisons

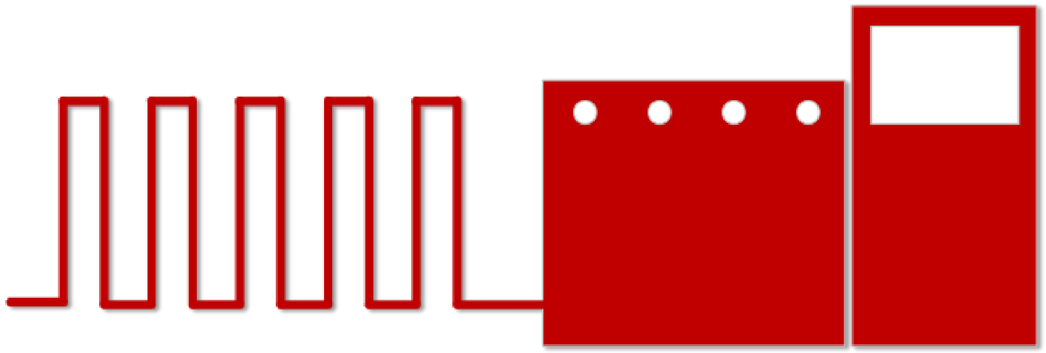
Still useful in answering *what* constituents are emitted

LIMITATIONS

Does not necessarily relate to real-world use

Therefore risks misrepresenting product performance

<u>Using puffing topography to determine our sampling regime gives more meaningful data</u>



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How to Measure Puffing Topography

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Video Assessment

- **Record/source videos of people using products and assess usage**

BENEFITS	LIMITATIONS
Minimal equipment required	Subjects have to remain in front of the camera for the duration
Can be less intrusive	Time-consuming to assess video
Good for counting the number or frequency of puffs	Can’t measure puff volume
	Inaccurate for puff duration

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Device Assessment

- **Certain e-cigarette devices have built-in software that have been used to directly record puff duration and puff counts**

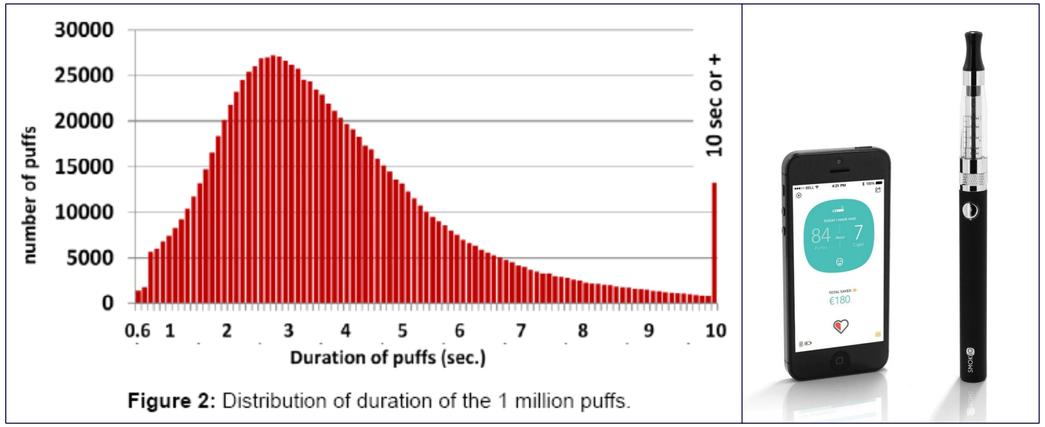

Figure 2: Distribution of duration of the 1 million puffs.

Data generated over 1 million e-cigarette puffs by 185 individuals using a Smokio tank e-cigarette [1]

Joyetech eVic supreme and myVapors software [2]

[1] Dautzenberg B, Bricard D. Real-time characterization of e-cigarettes use: the 1Million Puffs Study. *J Addict Res Ther*. 2015;6
[2] Dawkins LE, Kimber CF, Doig M, Feyerabend C, Corcoran O. Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects. *Psychopharmacology (Berl)*. 2016;233(15-16):2933-41.

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Device Assessment

BENEFITS

Least intrusive

Subjects are not limited to any test environment

Measures number, duration, and frequency of puffs

May also measure other device-related information (voltage, power, resistance)

Large amounts of data can be recorded and assessed relatively easily

LIMITATIONS

Usually can’t measure puff volume/flow rate

Requires specially designed e-cigarettes

Less useful if a specific product is required for assessment

Data consent needs consideration when existing customers are used

Validation/verification considerations when studies are scaled up

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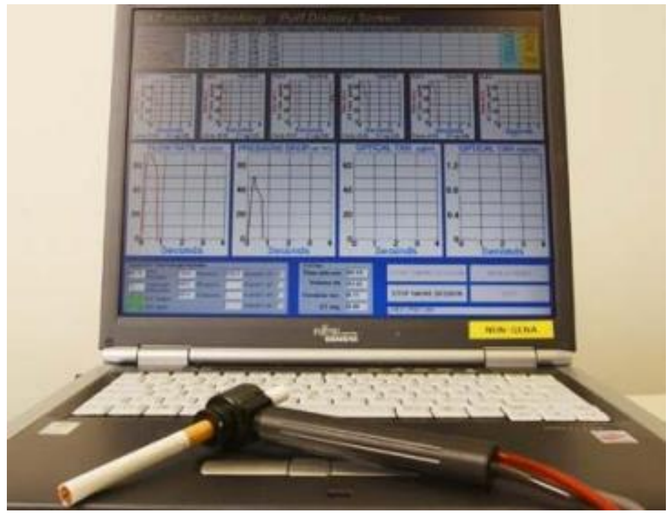
Specialist Measuring Devices

- Several devices are now commercially available or developed by individual academic/industry laboratories
- Usually equipment that is between the product and the user
- Generally measure flow-induced pressure drop
- Varying levels of portability

SPA-M (Sodim)

wPUM (Rochester Institute of Technology)



SA7 (British American Tobacco)

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Specialised Measuring Devices

BENEFITS

The best quality of data
- Puff volume, length, frequency, count, and continuous flow rate are all possible

Can generally be adapted to work on any inhaled product

Data can be processed automatically

Accuracy and precision can be quantified/verified

LIMITATIONS

Relatively intrusive (added equipment changes the experience for the user)

Subjects may be confined to a test environment for the study

The number of available devices limits the size of a study

Cost of devices may be prohibitive to the size of the study

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Summary of Measurement Techniques

- Which method should we use?
- They all have their strengths and weaknesses depending on resource and study scope

Measurement technique	Quality of Data	Adaptability	Cost	Intrusiveness	Portability	Scalability
	how good is the data we collect?	*how easy is it to adapt to different products?*	*what does it cost to set up a study?*	*how much does it change the natural experience?*	*how easy is it to use in a natural environment?*	*how easy is it to scale up a study?*
Video Assessment	medium	very high	very low	medium	medium	medium
"Smart" E-cigarettes	high	very low	low*	very low	very high	very high
Measuring Device	very high	high	high	high	low	low

Summary: How can Puff Topography Inform Emissions Testing?

- The way a user vapes has an effect on emissions generated
- To put emissions data into context, an exposure model can be used
- To make an accurate exposure model, emissions data must be generated in a representative way, standard puffing regimes may not reflect real-world use
- We can't assess this without some measurement of user behaviour (puffing topography)
- There are many approaches to measurement, each with benefits and limitations depending on resource and scope of requirements.

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Let’s collaborate

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