ELECTRONIC NICOTINE DELIVERY SYSTEM PUFFING TOPOGRAPHY CHARACTERISTICS FROM HUMAN STUDIES

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INTRODUCTION

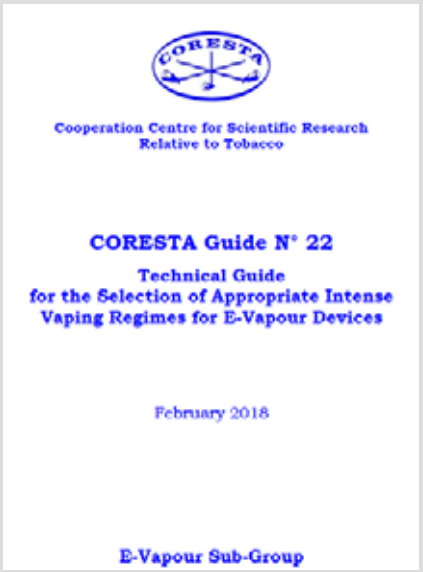
- The manner in which electronic nicotine delivery systems (ENDS) are used is a strong determinant of emissions
- Different puffing behaviours may differentially impact user exposure to chemical constituents
- Puffing topography information is important to determine puffing parameters for machine-generated yields
- Ideally, puff topography determination should be done prior to measuring ENDS emissions.

INTRODUCTION

- Puffing topography data are recommended for PMTA submissions, as outlined in the Guidance for Industry on Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, June 2019
    - *Section VI.G.9: "Assessment of user topography (how individual users consume the product, e.g., the number of puffs, puff duration, puff intensity, duration of use), the frequency with which consumers use the product, and the trends by which users consume the product over time"*

INTRODUCTION

- Some guidance is available on puffing parameters to use when measuring ENDS HPHC emissions



"….to provide guidance on which criteria should be considered when defining the required device and aerosol generation/collection system settings for intense use. Intense use can be regarded as the conditions which will result in higher levels of aerosol generation under normal use conditions (higher volumes of aerosol/higher exposure)"

INTRODUCTION

- CORESTA Guide No. 22 was published in early 2018 and an RAIS review was conducted Aug 2016; a significant number of topography studies have been reported since that time
- Aim of current project was to:
  - Examine literature published since issuance of CORESTA Guide No. 22 and conduct of RAIS review for relevant publications
  - Collate puff topography and other study data
  - Provide recommendations for machine puffing parameters

METHODS

- On May 2nd 2019, a PubMed search was carried out using specific syntaxes
- Searches were limited to August 2016-present and were checked for duplicates with previous CORESTA/RAIS reviews
- Of the total of 103 references identified using the syntaxes, 28 were PubMed search duplicates, leaving 75 references
- 6 references were removed as they were in the CORESTA/RAIS reviews

METHODS – EXAMPLE SYNTAX

- (“e cigarette” OR “e cigarettes” OR “electronic cigarette” OR “electronic cigarettes” OR “electronic nicotine delivery” OR “electronic nicotine device” OR “vape” OR "vaporiser" OR "vaporizer" OR “vaping” OR “e liquid” OR “Electronic Cigarettes” OR "e-cigar" or "e-pen" and "topography”)

METHODS

- References were screened for potential relevance

- Excluded materials included:
  - Review articles and protocols, survey studies
  - Non-human studies (e.g. *in vitro* or analytical studies, computational studies)
  - Studies using non-e-cigarette products (e.g. cigarettes, heated tobacco, waterpipe)
  - Studies not examining any topography parameters
  - Studies using topography measurements that were not described or were obtained from previous work

METHODS

- This left a total of 15 publications from which to obtain topography data
- One study (Mikheev *et al*., 2018) only provided estimates of device accuracy and recording errors
- Two further papers (Perkins & Karelitz, 2018 and Robinson *et al*., 2018) only provided data in graphical format that could not be used to populate quantitative data tables
- Son *et al*. (2019) presented the same data that had already been published by the same group (Son *et al*., 2018)
- Thus, 11 new and 18 previously identified papers (CORESTA and RAIS prior searches) were used for data collation

RESULTS

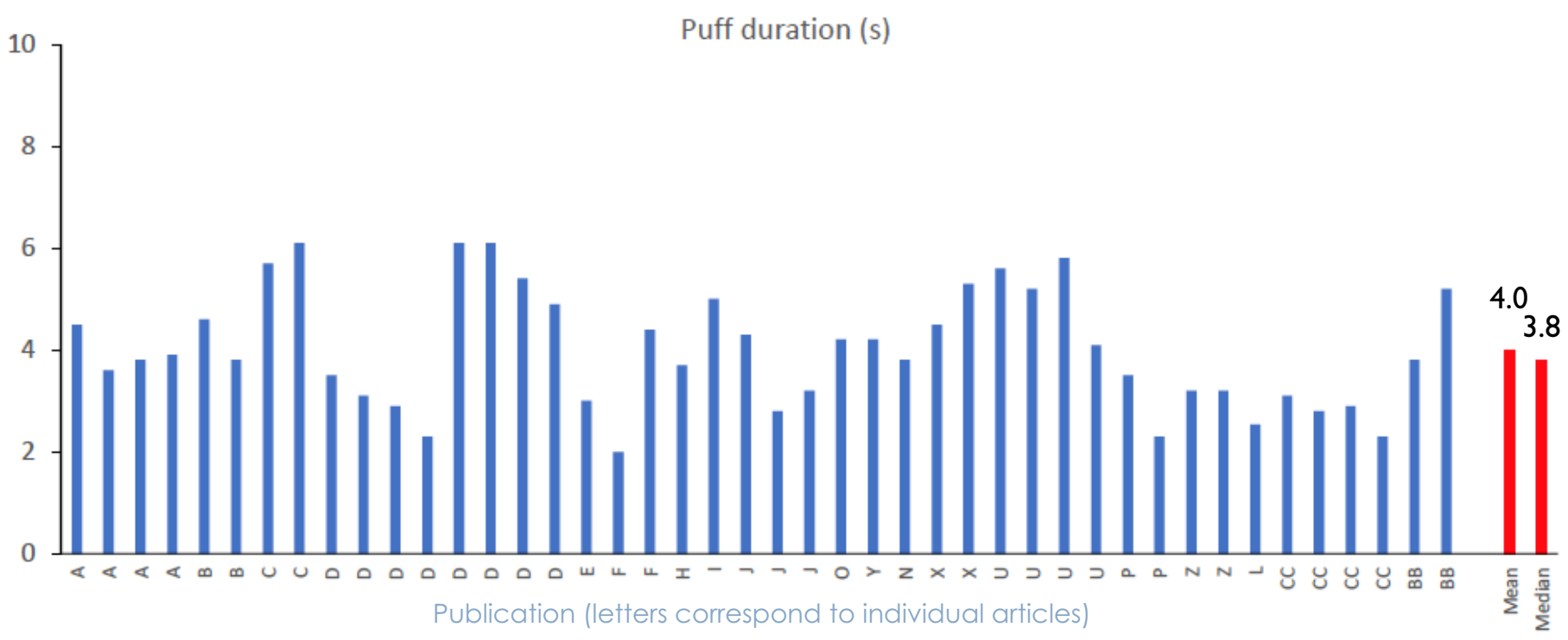
- The included publications were used to identify, where available, the following puffing topography parameters:
  - Puffs per day
  - Puffs per session
  - Puff duration
  - Interpuff interval
  - Puff volume
  - Flow rate

RESULTS

- Additional data were also collated:
  - Device type (tank, cig-a-like and pod)
  - Data collection conditions (naturalistic real-world or laboratory)
  - Number of participants
  - Method by which puffing topography data were collected (e.g. CReSS device, video analysis)

- For some studies, details of the device power output, e-liquid flavours, and nicotine strength were also included

RESULTS – TANK DEVICES



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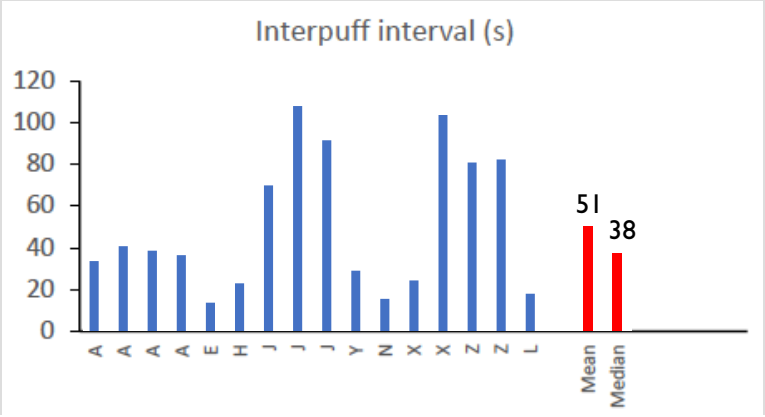
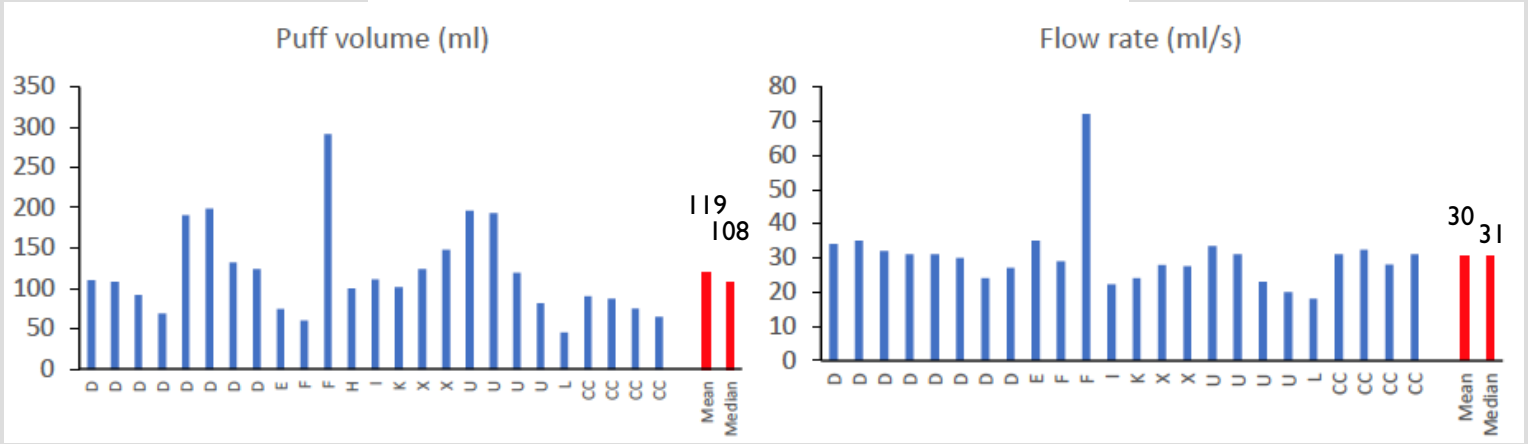
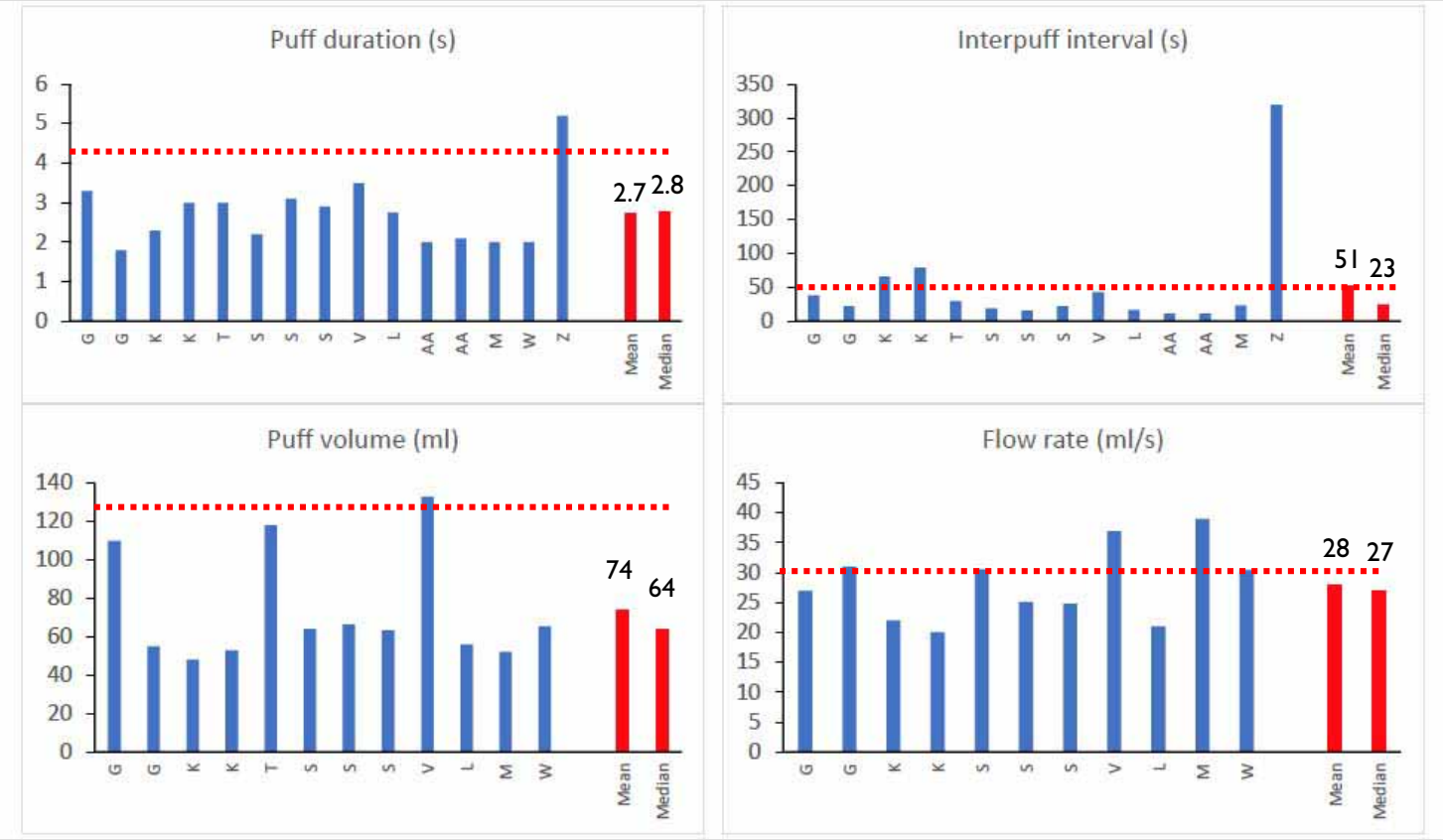




RESULTS – CIG-A-LIKE DEVICES

mean value for tank devices



RESULTS – CIG-A-LIKE DEVICES

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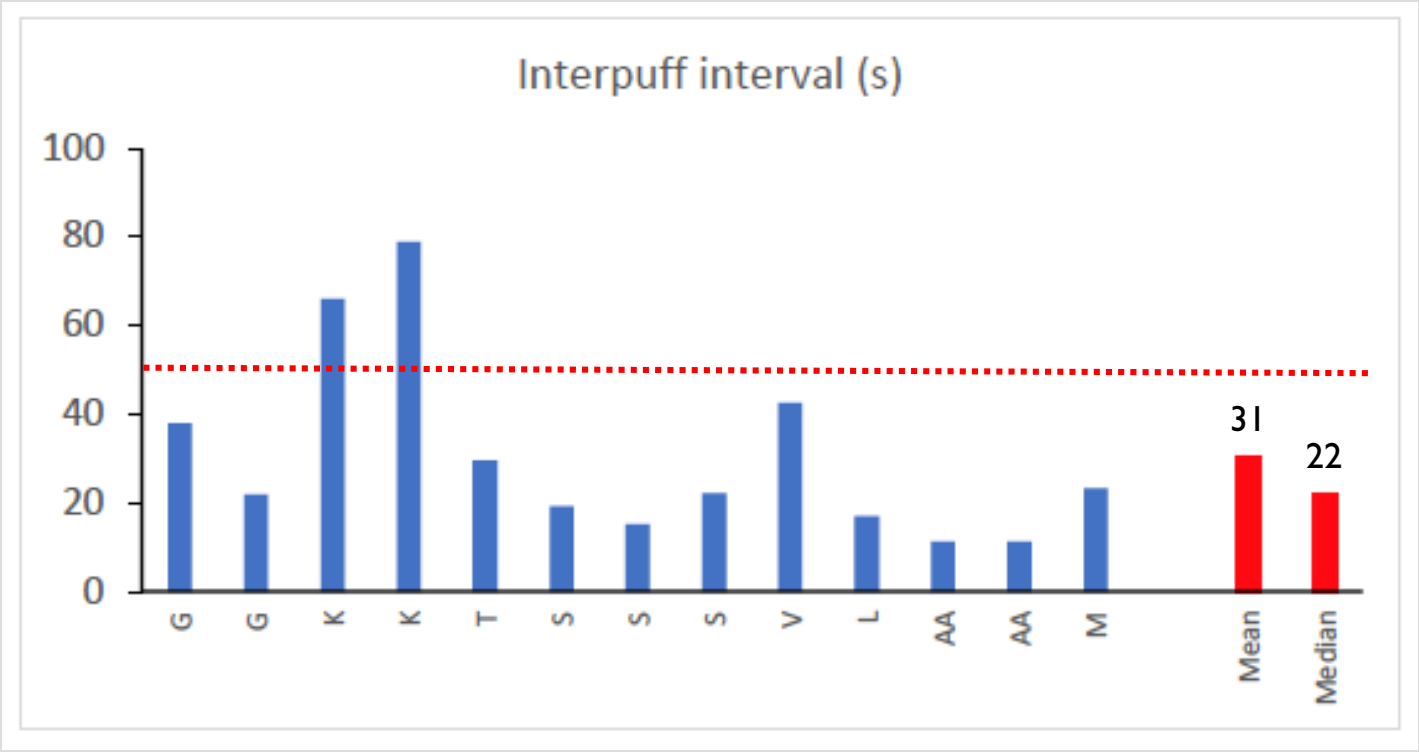

RESULTS – OVERALL DATA

Device type	Parameter	Mean	Median	Min	Max	Lower quartile	Upper quartile
Tank-style Cig-a-like	Puff duration (s)	4.0 2.7	3.8 2.8	2.0 1.8	6.1 5.2	3.1 2.1	4.9 3.1
	Interpuff interval (s)	49.7 30.5	38.3 22.1	5.2 11.2	107.0 79.0	24.9 16.9	84.3 38.0
	Puff volume (ml)	119.4 73.7	108.0 63.7	45.0 48.0	291.0 133.0	81.4 54.5	124.0 77.4
	Flow rate (ml/s)	30.4 28.0	30.5 27.0	18.0 20.0	72.0 39.0	26.3 23.4	31.4 30.8

RESULTS – OVERALL DATA

Non-intense regimen

Device type	Parameter	Mean	Median	Min	Max	Lower quartile	Upper quartile
Tank-style Cig-a-like	Puff duration (s)	4.0 2.7	3.8 2.8	2.0 1.8	6.1 5.2	3.1 2.1	4.9 3.1
	Interpuff interval (s)	49.7 30.5	38.3 22.1	5.2 11.2	107.0 79.0	24.9 16.9	84.3 38.0
	Puff volume (ml)	119.4 73.7	108.0 63.7	45.0 48.0	291.0 133.0	81.4 54.5	124.0 77.4
	Flow rate (ml/s)	30.4 28.0	30.5 27.0	18.0 20.0	72.0 39.0	26.3 23.4	31.4 30.8

RESULTS – OVERALL DATA

Intense regimen

Device type	Parameter	Mean	Median	Min	Max	Lower quartile	Upper quartile
Tank-style Cig-a-like	Puff duration (s)	4.0 2.7	3.8 2.8	2.0 1.8	6.1 5.2	3.1 2.1	4.9 3.1
	Interpuff interval (s)	49.7 30.5	38.3 22.1	5.2 11.2	107.0 79.0	24.9 16.9	84.3 38.0
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CONCLUSIONS

- Sparsity of 'pod' topography data in the literature
- For tank devices, users take longer puffs, of a much greater volume, but with a longer interpuff interval, than those using cig-a-like devices
- Flow rates similar between device types
- Many variables can affect topography – e.g. device power

CONCLUSIONS:
PARAMETERS DETERMINED FROM PUBLISHED DATA

- **Volume : duration : interval**

- **Tank-style devices**
  - Non-intense puffing: 80 : 3 : 60
  - Intense puffing: 125 : 5 : 25

- **Cig-a-like devices**
  - Non-intense puffing: 55 : 2 : 40
  - Intense puffing: 80 : 3 : 15

ACKNOWLEDGEMENTS

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