Smoking Behaviour Sub-Group (TSB)

2015 Report

05 October 2015

Jeju, South Korea

Smoking Behaviour Sub-Group

- Group originally set up as a committee reporting directly to the Scientific Commission, then became a Sub Group in 1996
- Typically meeting twice a year
- Tobacco & puffing topography device manufacturers; contract research, quality control & government laboratories; publisher and research institutes participate in collaborative studies
- <u>Executives:</u>
  - Coordinator: Dr Krishna Prasad (BAT)
  - Secretary: Dr Xavier Cahours (ITG)
  - SC Liaison: Dr Martin Blumenstock (BAT)

Outline 2015 Activities

- Remit change
- CRM80: Part filter method
- Topography device comparison study
- Abuse liability assessment update
- Reduced nicotine content cigarette review
- Standardised design for pharmacokinetic study
- Next steps
- Challenges

Smoke Science Study Group

- Remit extended:

- The Smoke Science Study Group is responsible for the scientific study of emissions from, and exposure to, tobacco and related products.
- This includes development of specific chemical and biological methods, and investigation of means to assess exposure and use.

TSB-SG Objectives

1. Critique and review published papers on all aspects of tobacco and related products' use behaviour, and publish in peer-reviewed journals.

2. Examine unpublished reports and work on the subject with a view to recommending publication of suitable papers in peer-reviewed journals.

3. Identify gaps in total knowledge and suggest suitable work to provide the necessary information.

In line with the change in remit, it is proposed to change the name from smoking behaviour to product use behaviour sub-group.

CRM80: Part Filter Method

- CRM80: Part Filter Method (PFM)

  - The CORESTA Recommended Method proposed for part filter analysis to estimate mouth level exposure to ‘tar’ and nicotine was prepared by Peter Clayton & Krishna Prasad – April 2015

  - CRM80 was modified to fit the CTR standardised template incorporating the SC’s feedback and resubmitted – September 2015

  - Awaiting final CORESTA Board approval

Topography Device Collaborative Study

Objective

- Compare the results from puff volume and puff duration measurements made using multiple units of four different topography devices by combining in a single concept (Accuracy Profile) the trueness and the uncertainty of laboratories and smoking topography devices.

1. Device Performance

How close is the average puff volume or duration:

- measured by the same device in a laboratory to the true value?
- measured by several units of the same device in a laboratory?

2. Device and Lab Performance

What is the maximum difference expected between two puff volumes or durations measured:

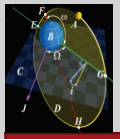
- using the same device in the same lab?
- using two different devices in two different labs?

Study Design

Devices/Parameters

4 Devices

Instrument	3 units (Serial n°)
CME P4	PP0002-0005-0006
CRESS Micro	002-003-005
SA-7	009-014-016
AM	179-180-182



3 Parameters

Parameter
Puff volume (ml)
Puff duration (s)
Average flow (ml/s)

Evaluation

2 Samples

Sample	Cigarette PD
WW	50 mmWG
CB	150 mmWG

4 Laboratories

Lab	Company
L1	R.J. Reynolds – USA
L2	ITG – France
L3	Sodim – France
L4	BAT – UK

Conditions

5 Smoking regimes

Smoking regime	Puff Volume (ml)	Puff Duration (s)	Average Flow (ml/s)
1	35	3.5	10
2	80	4.0	20
3*	90	3.0	30
4	80	2.0	40
5	50	1.0	50

* Repeated 4 additional sessions with one of each device across 4 separate days

2 Smoking modes

Mode	Number of puff
Lit	10 puffs: P_1 … P_{10}
Unlit	10 puffs: P_1 … P_{10}

Data Collation

- All 4 participating Labs have completed data collection and the master data file with all the study data has been compiled.
- Data Structure:
- Global device performance within and between labs

Labs	Cigs	Lit/Unlit	Dev	Units	Regimes	Puffs	Rows
4	2	2	4	3	5	10	9600

- Individual device performance within and between labs over a period

Labs	Cigs	Lit/Unlit	Dev	Unit	Regime	Days	Puffs	Rows
4	2	2	4	1	1	5	10	3200

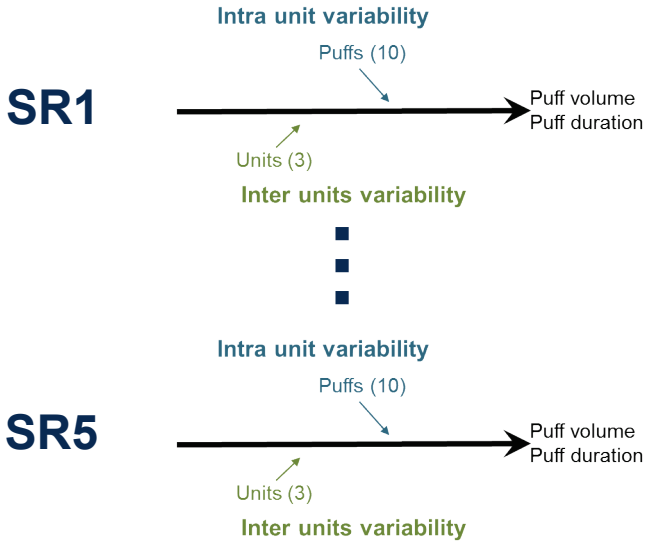
Device Performance Within & Between Labs

Lab / Device / Mode

Device Performance per lab

How close the average of measured puff volume or duration:

- measured by a same device in a same laboratory are to the true value?
- measured by several units of the same device in the same laboratory are?



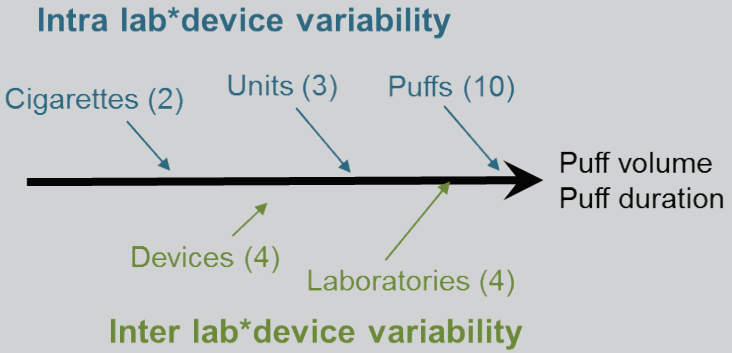
Accuracy Profile + Global index

Smoking Regime / Mode

Global Lab*Device performance

What is the maximum difference expected between two puff volumes or durations measured:

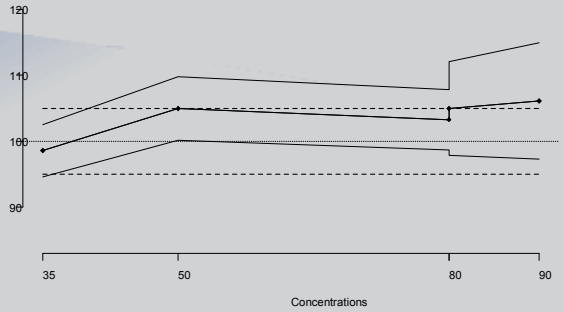
- using the same device in the same lab?
- using two different devices in two different labs?

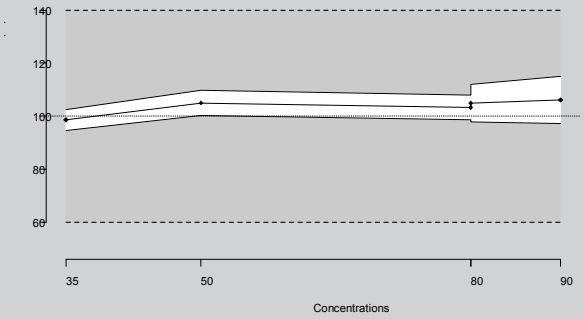


Intra lab*device repeatability (r*)

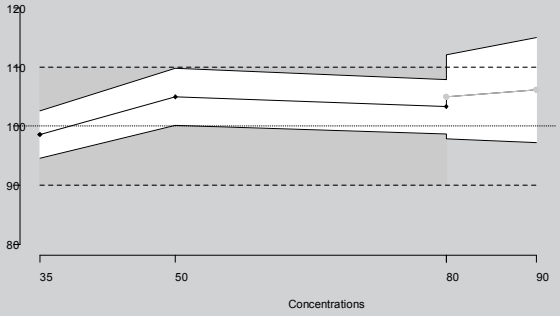
Inter lab*device reproducibility (R*)

Global Indices based on accuracy profiles

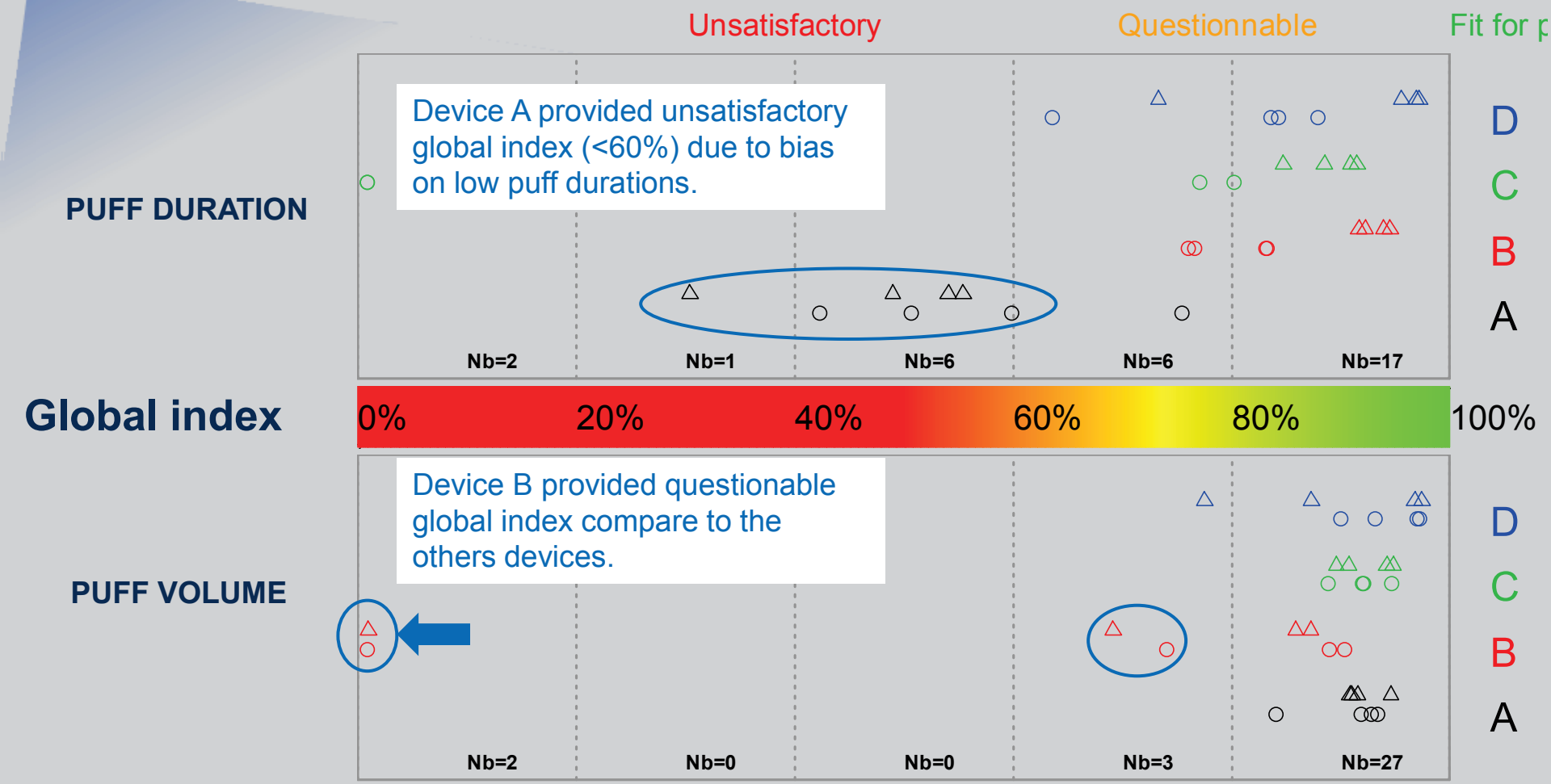




Global index



Global indices based on accuracy profiles



With a λ = 20%, all the devices cannot be considered as equivalent

Global Lab*Device performance

Smoking Regime	Target Duration	Average Measured Duration	CVr* (%)	CVR* (%)
5	1.0	1.01	12.3	26.4
4	2.0	2.04	12.0	20.6
3	3.0	2.90	11.8	18.2
1	3.5	3.15	4.0	17.6
2	4.0	3.74	8.0	15.1

Smoking Regime	Target Volume	Average Measured Volume	CVr* (%)	CVR* (%)
1	35	34.87	6.0	12.2
5	50	52.09	4.3	9.7
4	80	80.91	5.1	11.6
2	80	81.63	4.4	13.8
3	90	91.07	6.2	13.8

- Intra lab*device coefficient of variations ranged from 4% to 12%
- Inter lab*device coefficient of variations ranged from 10% to 26%
- Both intra and inter lab*device variabilities change non linearly with average flow rate

Abuse Liability Update

- We have maintained a “watching brief” on the issue of addictiveness/abuse liability with regular updates at TSB meetings

- Analysis of existing studies and available guidance suggests that the assessment of abuse liability involves of many factors no single test offers a complete characterization

- A questionnaire approach and pharmacological (PK) quantification of abuse liability, possibly supplemented with a human behavioural (preference) study, may be requested in the assessment of “addictiveness”

Reduced Nicotine Content manuscript

- The potential impact of mandated reductions in the nicotine content of tobacco and related products continues to be an issue of interest (*e.g. Donny EC et al. Randomized trial of reduced-nicotine standards for cigarettes. NEJM online, October 1 2015*)

- Work on a possible manuscript has been halted due to key staff movements

- It is proposed to allocate a new project manager with completion of this activity pushed to 2016

Standardised design for PK study

- **Objective:** Develop a document that summarizes strategies and best practices for pharmacokinetic measurement of nicotine in tobacco product use studies.

- **Considerations:**
  - Study objectives
  - Product type and route of uptake
  - Background correction and alternatives

- **Next Steps:** Identify members of writing group and propose project scope to scientific commission. (June 2016)

Next Steps

- Complete data analysis of Topography Device comparison study – Dec 15
- Draft study report for TSB-SG comments – Apr 16
- Identify SME to continue Abuse Liability Assessment update – Apr 16
- Propose review e-cig topography literature for TSB-SG to discuss – May 16
- Prepare Standardised design for PK study outline for SC consideration – Jun 16
- Propose e-cig topography collaborative study for TSB-SG to discuss – Jun 16

Challenges

Expand the activities of the SG to examine non-competitive issues surrounding public health, including:

- Consumer Risk Perception
- Abuse Liability
- Use behaviour to predict transitions
- Modelling of public health impact

We need to find a way of separating the underlying science and the different procedures used to arrive at a specified end point.

Any Questions?