**VALIDATION OF A NEW MODEL INFANT FACE WITH NASOPHARYNX FOR THE TESTING OF VALVED HOLDING CHAMBERS WITH FACEMASK AS A PATIENT INTERFACE**

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**BACKGROUND**

- The evaluation of Valved Holding Chambers (VHCs) with facemask cannot be performed in the laboratory without simulating the face in contact with the mask, including mimicking the soft tissue response
- Furthermore, the simulation of the upper airway permits assessment of dose delivered to the lungs
- Both are needed to provide reliable information to clinicians faced with dose titration in accordance with the GINA asthma guidelines

**STUDY PURPOSE**

- We report the evaluation of a new simulated model of a 7-month obligate nasal breathing infant
- This model has been established to establish the likely delivered fine particle mass (< 4.7 µm aerodynamic diameter (DFM <4.7 µm) of a beta2 agonist bronchodilator to the carina from a widely prescribed pMDI-VHC-facemask combination
- The magnitude of DFM <4.7 µm likely represents the portion of the dose that will reach receptors in the airways of the lungs

**STUDY DESIGN**

- Ventolin®-HFA, 100 µg/actuation albuterol (salbutamol) base equivalent ex pMDI valve
- 5-actuations at 30 s intervals/measurement
- GSK Canada Inc
- AeroChamber Plus® antistatic VHC with Flow-Vu* Inspiratory Flow Indicator (IFl) with infant (small) facemask
- Obturator used cut package with no pre-washing as they are made from electrostatic charge-dissipative polymer

**ADAM-III MODEL**

- Nasopharynx based on model 87 (Storey-Bishoff et al., 2008. J. Aerosol Sci. 39(12):1055-1065)
- Soft tissues together with the underlying rigid bone structure have been realized by a proprietary process
- Soft tissue modeling is essential if the correct fit of the facemask with appropriate internal dead volume is to be realized (Mitchell, J.P. 2008. J. Aerosol Med. 21(1):97-111)
- Determined FPF [<4.7 µm] = 100 (DM/LC * FPF<4.7 µm)
- The emission of aerosol particles was recovered from the system as follows
- pMDI actuator mouthpiece (MP)
- VHC interior, face enclosed by the mask including nostril entry (FACE)
- Nasopharynx (NP)
- In a parallel study, measurements of Aerodynamic Particle Size Distribution (APSD) were made replacing the filter of ASL 5000, IngMar Medical, Pittsburgh, PA

**RESULTS**

- Measures of mass % collected in each component of the pMDI-VHC and model (mean ± SD) summarized in the Table

<table>
<thead>
<tr>
<th>Run</th>
<th>MP</th>
<th>VHC</th>
<th>FACE</th>
<th>NP</th>
<th>FILTER</th>
<th>TOTAL</th>
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<td>0.6</td>
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<td>85.9</td>
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<td>4</td>
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<td>3.7</td>
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<tr>
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<td>3.0</td>
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<td>85.7</td>
</tr>
</tbody>
</table>

- Mass recoveries were slightly below label claim, most probably reflecting loss of medication during inhalation via the valve in the VHC facemask as well as limited analytical sensitivity
- Mass ablated/actuation depositing on the filter (DM/LC) was 3.7 ± 1.2 %

**DELIVERED FINE PARTICLE MASS**

- DFM<4.7 µm = 100 (DM - FPF<4.7 µm)/LC
- DFM<4.7 µm was therefore almost identical with DM at 3.6 ± 1.2 µg/actuation (3.6 ± 1.2 %LC)
- DFM<4.7 µm can be related to 1.97 ± 1.4 % lung deposition reported in the only scintigraphic study of airway-obstructed infants and small children
- Mean age 21 months
- Radio-labeled ablated delivered by pMDI-AeroChamber® VHC

**CONCLUSIONS**

- The ADAM-III model is capable of being used as a new tool to assess accurately the mass of pMDI-delivered medication that might reach the lungs of a tidal-breathing infant
- This model is capable of providing clinically relevant data for use in delivering pMDI-based aerosol medication to this obligate nasal breathing infant population