



## WHICH FACE MASK DESIGN IS ASSOCIATED WITH IMPROVED DRUG DELIVERY TO THE LUNGS?

by *Herbert Patrick MD*

The peer-reviewed research article selected to teach the Scientific Method for this issue of FOCUS is: Keith W. Harris, M.D. and Gerald C. Smalldone, MD, Ph.D. Facial and ocular deposition of nebulized budesonide - effects of face mask design. Chest, February 2008; Volume 133: Number 2, pages 482-488. Both authors are from the Division of Pulmonary, Critical Care and Sleep Medicine, Department of Medicine, State University of New York, Stony Brook, New York.

The Background or Introduction of the research project explains interest in the topic and why the topic is significant. The authors state that aerosolized therapy using a face mask deposits droplets in the lungs but also on the face and in the eyes due to the nature of aerosol escaping from the edges of the mask. The authors note that depending on the drug being aerosolized, entry

into the eyes may result in pupil dilation and glaucoma. To study the aerosol in a laboratory setting, instead of the bedside, requires a face and face mask model that ventilates like a patient. The authors describe a custom made model of a child's face with an oral breathing pattern provided by a piston pump

connected behind the mouth. This mannequin system was used for this study of various mask and nebulizer combinations. The Question being asked by the researchers is: Does face mask design influence the behavior of inhaled medication? Note: The Question asked in a research project may have the possible answers: "yes" and "no," as in this study, or may be a numerical result. The preconceived answer by the researchers to the Question is called the Hypothesis. Although the researchers did not indicate their hypothesis, those with experience might propose: yes, face mask design influences the behavior of inhaled medication. The Methods for the research project describe the study design, setting and steps to answer the Question. The authors used an in-vitro design, meaning the study was conducted in a laboratory without human subjects. A study with humans would be called an in-vivo design. Since this research did not involve human subjects, the authors did not need Institutional Review Board (IRB) approval. The set-up in their laboratory used the child's simulated face designed with an oral opening as a substitute for a mouth. Aerosol to the mask was generated by various nebulizers connected to a compressor. The inspiratory and expiratory pattern of respiration at the simulated mouth was provided by the piston pump with a pediatric breathing pattern of 50 mL tidal volume and 25 breaths per minute. Aerosol drug particles passing through of the mannequin's mouth were measured by deposition on an inhaled mass filter connected behind the mouth. Aerosol deposition over the eyes was determined by measuring the quantity of drug deposited on filters placed over the eyes of the mannequin. Aerosol deposition on the face was determined by measuring the quantity of drug deposited on filters placed on the face of the mannequin. The drug chosen by the authors, budesonide suspension (Pulmicort Respules; AstraZeneca LP; Westborough, MA), was tested at the standard dose of 0.5 mg in 2.0 mL of normal saline. Each different mask and nebulizer combination was tested in triplicate with cumulative aerosol deposition measured in the inhaled mass filter behind the mouth, on the filters over the eyes, and, on filters on the face. The triplicate process was combined to represent a single data point with the authors

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**Does face mask design influence the behavior of inhaled medication?**

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**"I think we're overanalyzing. Give it some thought."**

obtaining two data points for each different mask and nebulizer combination.

The authors studied straight in, or "front loaded" masks connected to the nebulizer via a 90 degree elbow, and "bottom loaded" masks that have a lower connection to the nebulizer.

The statistical analyses were based on equal budesonide amounts loaded into the nebulizer for delivery to the mannequin ("patient") for each experiment. The authors reported results as a percentage of nebulizer charge and compared the "front-loaded" versus the "bottom loaded" set-ups.

The Results section compiles the data to answer the Question. The authors' review of the data from the "front loaded" and the "bottom loaded" set-ups was displayed in a table with rows for inhaled mass, eye deposition, and facial deposition. Mask design was the dominant factor affecting aerosol delivery of budesonide suspension through the mannequin mouth, onto the eyes, and onto the face. "Front loaded" masks delivered more drug through the mouth and less to the eyes and face than "bottom loaded" masks.

The Discussion/Reflections/Future Research starts with a summary Discussion of the research. In this research project, the authors noted that particle inertia along the edge of the mask explains eye and facial deposition. A tight-fitting mask could actually allow aerosol to escape at higher velocities than a loose-fitting mask. High velocity aerosols are more likely to deposit on the eyes and on the face. The Reflections are a comparison with similar research projects and a critique by the authors of their own research project. The authors note that no mannequin can be expected to reproduce all possible faces, or, in fact, any living face. The authors explain the selection of the nebulizers were for efficiency and constant flow. Future Research describes modifications to the project or new projects that would contribute to this research topic. The authors note that studying the face mask as a device rather than as a simple connector to the face is new and evolving.

The Conclusion is the final summary of the research project. This research project demonstrated that "front loaded" mask delivered less to the eyes and face than "bottom loaded" masks. Therefore, in this research project, the Question was properly addressed. The proposed hypothesis was correct.

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Conflicts of Interest are listed for all participating in authorship of the article for the research project. Conflicts include advisory board mem-

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The Bibliography section includes references to support the research as included in the manuscript by reference number. For this research project, there were seventeen references.

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