DETECTING ERRORS IN USING METERED DOSE INHALERS (MDI) AMONG ASTHMA AND COPD PATIENTS

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Section C: Background

Obstructive lung disease is associated with significant morbidity and mortality worldwide [1]. Asthma and chronic obstructive pulmonary disease (COPD) comprise two of the largest groups of obstructive lung disease [1], impacting nearly 510 million globally [5]. About 255,000 people die from asthma each year [2], and 80% of these deaths occur in low and middle--income countries [3]. Asthma continues to be the most common chronic disease among children [4]. COPD is expected to become the third leading cause of death worldwide by 2030 [2].

The treatment for Asthma and COPD patients consists of a combination of controller and rescue medications. The control (maintenance) medication is taken daily (once or more, based on prescription) to keep the disease symptoms in control and avoid reaction towards triggers that cause exacerbations (asthma attacks). The rescue (also sometimes referred as emergency) medication is used during an exacerbation. The rescue medication provides temporary relief and has higher efficacy if the patient is compliant with the daily control medication regime.There is a strong clinical evidence that regular use of the controller medication minimizes long--term damage to the lungs, and results in improved health outcomes for the patients [6, 7, 15]. Additionally, regular, effective dosing of asthma inhaler medication leads to well controlled asthma, reflected as low incidences of asthma--related exacerbations, hospitalizations and deaths.

Metered Dose Inhaler (MDI) and Dry Powdered Inhaler (DPI) are the two most common platforms to deliver medicine for patients suffering from Asthma and COPD, and are used for dispensing both controller and rescue medications. Despite well--known methods to manage Asthma and COPD, nearly 70--90% of the patients do not display correct technique in using an inhaler [8--14, 15]. Poor management and control of the disease due to inadequate inhaler usage has resulted in rising rates of hospitalizations, making chronic respiratory diseases among the top five causes of death worldwide. Through this study we aim to record the technique of MDI usage among Asthma and COPD patient and understand the errors in their technique. The various parameters of inhaler usage where patients can make an error are 1. Tidal volume, inspiration flow rate, 3. Inspiration flow volume, 4. Timing of actuation of inhaler and 5. Breadth holding. The parameters will be recorded for each patient and the errors in each MDI usage will be noted. Using ex--vivo modelling, the patient's MDI technique recorded will be used to study the impact of errors in technique on efficiency of MDI drug delivery.

Section D: Purpose and Objectives

The purpose of this research is to quantify the impact of errors in MDI usage technique on the lung deposition of the medication. In order to achieve the above goal, we will conduct the current study to electronically measure the MDI usage technique by patients, before and after coaching by a trained technician or Doctor, in a clinic environment.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender: Both

Age: Adult (18--64 yrs), Geriatric (65+ yrs)

Ethnicity: All Ethnicities

Primary Language: English, Spanish

Groups to be recruited will include: Patients

Vulnerable populations to be recruited as subjects: Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

No vulnerable populations will be recruited

E3. Pregnant woman/fetus

Will pregnant women be enrolled in the research?

No

E4. Neonates

Will neonates be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

d) Questionnaire/survey/interview

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

This trial is an observational study aimed at capturing and understanding the errors made by Asthma and COPD patients in their technique of using an MDI. The patients will take a dose from a placebo MDI attached to an electronic flow meter to record their usage before and after receiving instructions on how to use the inhalers. The MDI usage data will be used for further in--vitro studies to understand efficacy of MDI and lung deposition.

There is no randomization of subjects. We will be recording the patients use of a placebo inhaler attached to an electronic flowmeter.

Inclusion Criteria:

1. Patients with a physician diagnosis of asthma or COPD taking inhaled medications using MDI

2. Age >18 years

3. Able to read and sign consent document.

Exclusion Criteria:

1. Patients having acute exacerbation

2. Patients who are unable to take medication from an MDI

F2. Procedure

The study will be offered to asthma and COPD patients arriving at the Harris Health Smith Pulmonary Clinic or at the PFT lab at Ben Taub Hospital. Potential subjects will be asked if they are interested and if they currently use MDIs to take their medicine. The subject will be given time to read and ask questions about the study. After obtaining signed consent, the technician or medical staff member will oversee and guide the subject through the study.

The subject will be given a placebo MDI with an electronic attachment consisting of a flow meter, force sensor and microcontroller to record the inhaler usage parameters such as inspiration/expiration flow rates, flow volumes, MDI actuation and breadth hold. A checklist will be developed which clearly states all the steps for using an MDI. The checklist will be coded by a serial number for the patient such that the subject's name or other personal identifiers are not recorded.

The subject will be asked to perform a sample MDI dosing using the placebo MDI attached to the electronic monitor described above. The patients will only inhale from the MDI--flowmeter setup. Each MDI--flowmeter setup has a separate disposable mouthpiece for each patient. The electronic monitor will send all the data collected during MDI dosage through Bluetooth to the study team's android phone or computer and store the information for each dosage in the coded format of the checklist (serial number). The staff will record the validity or errors in each step of MDI usage in the checklist.

Next, the subject will be given a short education session on how to correctly use an MDI. The subject will perform another MDI dosage maneuver with the placebo MDI attached to the electronic monitor. The second dosage, after training by the staff, will be recorded and stored in the phone or computer. The staff will again record the validity or errors in each step of MDI usage in the checklist.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 120 Worldwide: 120

Please indicate why you chose the sample size proposed:

Since this is an observational study, the aim is to record a variety of MDI usage techniques performed by patients. We are recruiting patients from age 18 and above. We will be dividing the patient population into five age groups of: 18--32, 33--47, 48--62, 63--77, 78 and above. We expect to recruit at least 20 patients from each group and hence, the number of subjects is at least 100. We have chosen 120 to

account for the fact that some groups may have more patients and we may record more than 20 patients for those age groups.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

First, we will extract and separate the information about inhalation flow rates, timing and MDI actuation from the raw patient data collected from this study. The post processed patient data will not undergo any inference or analysis. The data collected from each patient will serve as input to a 'In--Vitro Lung Deposition Experiment'. The patient data represents the MDI usage of a patient, and each patient data point collected in this study will be fed into the 'In--Vitro Lung Deposition Experiment' to understand lung deposition of medication for that patient. Thus, this study is only aimed at collecting the different types of MDI usages by Asthma and COPD patients.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts and assess the likelihood and seriousness of such risks: Participants will use placebo MDIs (inhalers without active medication) during the study. There is a very slight risk that the propellant in the placebo metered dose inhaler could cause bronchospasm. All subjects will be monitored for this occurrence and will be give a short--acting bronchodilator immediately if this occurs.

A separate mouthpiece system will be used to make sure there is no contamination between patients. The participant may find some minor discomfort in using the MDI-- flowmeter setup since it is different than the normal MDI. The medical staff conducting the study will guide the participants to make the process easier.

There is minimal risk of loss of confidentiality. The patient's name or birthdate will not be entered in the electronic recording. The subject number is coded as a serial number. We will record the gender, age, height and weight of each patient, as part of the testing information. No other personal, patient identifiable information will be collected.

All subjects are free to end their participation in the study at any time they wish.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi--site research

Is the BCM Principal Investigator acting as the SPONSOR--INVESTIGATOR for this multi--site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi--site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefits to be gained by the individual subject as a result of participating in the planned work.

The patient will receive additional training on the use of an MDI by the technician or medical staff. In turn, this can improve the subject's ability to take their medication properly.

Describe potential benefits to society of the planned work.

This study will help the study doctors and research team understand more about which steps in the proper use of the metered dose inhaler can impact treatment of patients with asthma or COPD.

Do anticipated benefits outweigh potential risks? Discuss the risk--to--benefit ratio.

The risk is minimal thus the anticipated benefits outweigh the potential risks. The risk to benefit ratio weighs on the side of benefit.