Evaluation of the Knowledge and Correct use of Metered Dose Inhalers by Health Care Professionals and Medical Students in Gauteng.

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A research report submitted to the University of Witwatersrand, Johannesburg in fulfilment for the requirements of the degree of Master of Medicine, 2016.
DECLARATION

I, Hlanjwa Modipadi Maepa; hereby declare that this research is of my own work. I am submitting this research report for the degree Master of Medicine (in the submissible format with my protocol and extended literature review) in the branch of Internal Medicine at the University of the Witwatersrand, Johannesburg. This research report has not been submitted before for any degree or examination at this or any other university.

...........................................

........day of ..................2016
ACKNOWLEDGEMENTS

I would like to thank my supervisors Prof. Michelle Wong and Prof. Colin Menezes for their support and patience during this research project. I have the utmost gratitude to you both.
To my husband, my two beautiful children and the rest of the extended family, a huge thank you for your unconditional love and support. I would not have achieved any of this without you.
ABSTRACT

Background

Uncontrolled asthma and chronic obstructive airway disease (COPD) is a frequent cause of emergency department visits and hospital admissions. Poor metered dose inhaler (MDI) technique is likely a major contributory cause.

Objectives

This study evaluated study participants' knowledge of MDI technique, and their compliance in checking and demonstrating MDI use, to patients on inhaled therapy.

Methods

A questionnaire was administered to doctors, nurses, and final year medical students at Helen Joseph Hospital and Chris Hani Baragwanath Academic Hospital in the Departments of Internal Medicine, Emergency Medicine and Pulmonology. Participants' use of a placebo MDI was also evaluated by a scoring system.

Results

The total sample of 195 participants comprised 130 (67%) females and 65 (33%) males. Of these, 133 (68%) were qualified medical staff, and 62 were final year medical students. Only 32 (16%) had adequate MDI technique. Over 50% of participants did not demonstrate MDI technique to patients, or check their patients' technique.
Conclusion

Health care professionals (HCPs) and final year medical students have poor knowledge of inhaler technique and are ill-prepared to teach patients. Also of concern is that the majority do not routinely demonstrate or observe patients’ inhaler technique.
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<tr>
<td>CHBAH:</td>
<td>Chris Hani Baragwanath Academic Hospital</td>
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<td>COPD:</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<td>GINA:</td>
<td>Global Initiative for Asthma</td>
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<td>GOLD:</td>
<td>Global Initiative for Obstructive Lung Disease</td>
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<td>HCP:</td>
<td>Health Care Professional</td>
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<td>HJH:</td>
<td>Helen Joseph Hospital</td>
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<td>ICS:</td>
<td>Inhaled corticosteroids</td>
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<tr>
<td>LABA:</td>
<td>Long-acting beta agonist</td>
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<td>LAMA:</td>
<td>Long-acting muscarinic antagonist</td>
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<tr>
<td>MDI:</td>
<td>Metered dose inhaler</td>
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<tr>
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<td>South African Thoracic Society</td>
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CHAPTER 1: PROTOCOL AND EXTENDED LITERATURE REVIEW

1. 1 Introduction and Background
The prevalence of chronic airway disease is increasing in all parts of the globe. Three hundred million people have asthma and 210 million people have chronic obstructive pulmonary disease (COPD) worldwide.1-2

1. 2 Asthma
1. 2.1 Definition
Asthma is defined as a chronic inflammatory disease of the airway. It is characterized by reversible narrowing of the airway, resulting in obstruction of airflow in susceptible individuals, secondary to exposure to a stimulus e.g. cold air, dust mites, air pollutants, and even anxiety. The WHO defines asthma as an inflammatory disease characterized by recurrent attacks of breathlessness and wheezing.3 It is a complex interaction of airflow obstruction and bronchial hyper-responsiveness. The severity and frequency of attacks varies from individual to individual.3

1. 2.2 Pathogenesis
Genetics play an important role in the development and maintenance of asthma. There is a higher concordance in twins, and similarly an increased incidence in first degree relatives. Atopy predisposes individuals to develop an immunoglobulin E (IgE)-mediated response to common inhaled allergens. It is also the strongest identifiable predisposing factor for developing asthma.4-5
In asthma, exposure to allergens or known triggers, results in immunohistopathological changes to the bronchial mucosa. There is a significant influx of inflammatory cells such as eosinophils, lymphocytes, mast cells and neutrophils (especially in acute, fatal attacks and smokers), leading to epithelial cell injury. Structurally, there is thickening of the bronchial wall and narrowing of the bronchial lumen. Ongoing inflammation contributes to airway hyper-reactivity and hyper-responsiveness, decreased airway patency due to airway oedema, chronic respiratory symptoms which can lead to an acute asthmatic attack and ultimately, airway wall remodelling.4-5

Asthma should be treated early and appropriately. This prevents continuous changes to airway structure resulting in sub-basement membrane fibrosis, increased mucus secretion with formation of mucus plugs, smooth muscle hypertrophy and formation of new blood vessels that proliferate and dilate abnormally. Airway repair is not well regulated.4-5 This contributes to the chronicity of asthma as well as to limitation in therapeutic response.5

1. 2.3 Asthma related complications

Severe, uncontrolled asthma may lead to recurrent emergency department visits as well as hospitalization. This impacts negatively on quality of life with increased number of sick days from work or school, and inability to take part in recreational activities.

The structural changes that occur with asthma, i.e. narrowing of the airways and mucus hyper-secretion, affect how well an individual can breathe and may lead to respiratory failure. In rare cases, asthma may lead to life-threatening respiratory complications such as pneumothorax with lung collapse which can be fatal. This requires urgent insertion of an intercostal drain. Asthma may lead to death even without pneumothorax. Repeated
endotracheal intubations for acute asthmatic attacks may lead to life-threatening tracheal stenosis, requiring surgical intervention in the form of tracheostomy to enable adequate upper airway patency.\textsuperscript{6}

Inhaled corticosteroids (ICS) are the cornerstone of pharmacotherapy in asthma. They, however, can cause local and systemic adverse effects. Local effects include sore throat, hoarse voice and oral candidiasis. All patients on inhaled corticosteroids are encouraged to rinse out their mouths and brush their teeth after use of ICS, to reduce the above-mentioned local effects. The development of oral candidiasis may require treatment with topical antifungal therapy.\textsuperscript{7}

Systemic effects of ICS are dose-related, and may be more obvious in patients with co-existing diabetes mellitus, osteopaenia or established osteoporosis. Patients on high dose ICS (i.e. \textgeq 1000mcg beclomethasone dipropionate or equivalent) are at an increased risk of developing type 2 diabetes mellitus and its associated complications. Other serious complications include the development of tuberculosis and fractures due to osteoporosis.\textsuperscript{7}

1. 2.4 Management

The four components of asthma management include measures of (1) assessment and monitoring, (2) patient education for an efficient partnership in asthma care, (3) identifying and controlling environmental factors and co-existing conditions that may affect asthma, and (4) pharmacological therapy.\textsuperscript{5} The Global Initiative for Asthma (GINA) advises that asthma treatment is adjusted in a continuous cycle. This includes assessment of the asthmatic patient, adjusting treatment and reviewing treatment response.\textsuperscript{8}
Assessment of asthmatic patients includes a thorough history of symptoms and their frequency, a history of co-existing conditions e.g. gastro-oesophageal disorder, and a thorough physical examination.\textsuperscript{8-9} Of great importance is to assess the patient's inhaler technique and level of adherence. A lung function test, especially forced expiratory volume in 1 second (FEV\textsubscript{1}), aids physicians in assessing whether there is disease control, and informs them on the need for adjustment in the treatment plans for patients. FEV\textsubscript{1}, especially if <60% predicted, is a modifiable independent risk factor for asthmatic exacerbation.\textsuperscript{8} Patient preference for the inhaler device (i.e. metered dose inhaler (MDI) with or without a spacer device, dry-powder inhaler etc.) is also important, as well as the formulation of a comprehensive patient-physician treatment plan.\textsuperscript{8}

Adjustment of treatment is a discussion between patient and physician. Risk factors must be identified (e.g. occupational factors affecting disease control, obesity etc.), and modified accordingly. Non-pharmacological strategies (i.e. avoidance of identified triggers, weight loss, and cessation of smoking) should also be implemented. This requires full compliance from the patient to ensure improvement in lung function, as well as reduction of symptoms.\textsuperscript{8}

Treatment response review is dependent on the patient's symptoms, frequency of asthmatic exacerbations, drug side-effects and overall patient satisfaction. Objectively, a lung function test aids in informing the physician whether disease control is optimal.\textsuperscript{8-9} The Asthma Control Test is a questionnaire based tool that provides a numerical score, helping physicians determine whether symptoms of patients are well controlled. This test assesses the patient's perception of how well their asthma is controlled, as well as the degree that their asthma affects their functioning at work and home life. The patient's morning and nocturnal symptoms, degree of dyspnoea, and the frequency with which relieving inhaled medication is
used, is also assessed during the test. A score above 20 indicates good asthma control, whilst that below 15 indicates poor control. A change of more than three points when compared to previous scores is regarded as significant and aids physicians in deciding the best next step in the management of the patient.

A step-wise approach to asthma treatment is advised by GINA and the South African Thoracic Society (SATS).\(^8\)\(^9\)Asthma pharmacological therapy is an evolving combination of preferred controller agent and a reliever agent. GINA uses a 5step approach, starting patients on an initial regular dose of ICS adjusted for the level of severity, together with a short-acting beta agonist (SABA) on an as-needed basis. Depending on disease control and lung function, treatment will be escalated step-wise to include a medium or high dose ICS and a long-acting beta agonist (LABA). Leukotriene receptor antagonists and tiotropium are considered as alternative additional controller agents. A combined low dose ICS and formoterol inhaler, prescribed both for maintenance and reliever therapy, is recommended for patients with frequent exacerbations despite other treatment.\(^8\)

Patient education on the disease itself, inhaler technique, drugs used and their side-effects is important for both the physician and patient. This promotes a good open relationship and fosters treatment plan adherence.

1.3 Chronic Obstructive Pulmonary Disease (COPD)

1.3.1 Definition

The Global Initiative for Obstructive Lung Disease (GOLD) defines COPD as a preventable and treatable disease. It is associated with significant non-pulmonary effects that add to disease severity in patients. It is characterised by airflow obstruction that is often not
It is most commonly related to smoking tobacco, and develops later in life. It is a progressive disease with an abnormal, poorly regulated inflammatory response of the lungs to noxious particles or gases.\textsuperscript{11}

COPD is characterised by dyspnoea, chronic cough and chronic sputum production. Spirometry is required to confirm the diagnosis. A post-bronchodilator FEV\textsubscript{1}/FVC (forced vital capacity) ratio < 0.7 confirms airflow limitation, and is highly suggestive of COPD in the correct context. Severity classification of COPD depends on the presence of FEV\textsubscript{1}/FVC<0.7 plus an FEV\textsubscript{1} \geq 80\% predicted (GOLD 1, mild COPD), 50-80\% predicted (GOLD 2, moderate COPD), 30-50\% predicted (GOLD 3, severe COPD), and \leq 30\% predicted (GOLD 4, very severe COPD). Very severe COPD is also defined as FEV\textsubscript{1}<50\% predicted with chronic respiratory failure.\textsuperscript{11}

\subsection*{1.3.2 Pathogenesis}

In COPD, the normal inflammatory response is exaggerated with excessive release of neutrophils, macrophages and elastases. This results in destruction of large (central) airways, the small (peripheral) bronchioles, and the lung parenchyma.\textsuperscript{11}

Smoking causes production of free radicals due to the increased oxidative stress. The oxidants released by phagocytes lead to premature cell death or necrosis of exposed cells. Accelerated aging and autoimmune mechanisms have also been suggested as having roles in the pathogenesis of COPD.\textsuperscript{11}

COPD is often a combination of chronic bronchitis or emphysema. In some cases, patients may have a mixture of both diseases. Emphysema is a histopathological diagnosis defined by
permanent enlargement of airspaces distal to the terminal bronchioles. Panacinar emphysema usually develops in individuals with already a genetic predisposition to alpha 1-antiprotease deficiency. Emphysema leads to loss of alveolar surface area resulting in impaired gaseous exchange. There is also a decrease in elastic recoil, further worsening airflow limitation and narrowing.11

1.3.3 Complications

COPD is progressive with worsening respiratory symptoms and poor quality of life. Ventilation-perfusion mismatch in the alveoli occurs due to structural damage of lung parenchyma and blood vessels. The formation of bullae due to underlying emphysema may occur, leading to spontaneous pneumothoraces.

Hypoxaemia leads to pulmonary vasoconstriction and also secondary polycythaemia. The latter, in turn, leads to hyperviscosity, increasing the risk of patients developing thromboses. This may include deep venous thromboses, pulmonary thrombo-embolic disease and strokes. Life-threatening conditions such as coronary artery disease may further complicate the management of COPD.11

With impaired ventilation, hypercapnia ensues, causing respiratory acidosis. This contributes to hypoxia-induced pulmonary artery vasoconstriction and the development of cor pulmonale. There is significant strain on the right ventricle of the heart, with severely compromised patients developing features of right heart failure. With increasing severity of COPD, recurrent exacerbations and repeated chest infections occur frequently. This adds to the morbidity of COPD, making it more difficult to improve patient symptoms and quality of life.
Domiciliary oxygen is required in severe COPD, with worsening respiratory symptoms, declining lung function and intractable respiratory failure.\textsuperscript{11}

\textbf{1. 3.4 Management}

As for asthma, a full history and thorough physical examination of patients is mandatory. The identification of co-existing or emerging systemic manifestations of COPD is important. Lung function tests, application of the Modified Medical Research Council Dyspnoea Scale and evaluation of exacerbation risk (combined assessment of COPD) aids physicians in classifying the severity of COPD adequately and therefore deciding on best treatment plans for patients. The aim is to reduce the number of exacerbations, improve quality of life and reduce mortality.\textsuperscript{10-11}

The non-pharmacological measures of COPD management include smoking cessation. Patient and family education is key, as well as enrolling in support groups. Psychosocial support is important in these patients as they are prone to depression. In addition, chest physiotherapy and physical therapy with bronchopulmonary hygiene is important. A well-tolerated exercise programme, as well as vocational rehabilitation is recommended to further improve outcomes for patients with COPD.\textsuperscript{10-11}

Pharmacological therapy depends on the combined assessment of COPD.\textsuperscript{10} This is dependent on severity of symptoms, FEV$_1$ % predicted and history of exacerbations. These 3 factors determine the allocation of patients into class A (low risk of exacerbations, relatively mild symptoms), B (low risk of exacerbations, more severe symptoms), C (high risk for exacerbations, relatively mild symptoms) or D (high risk of exacerbations, more severe symptoms). Patients with mild symptoms and low exacerbation risk require bronchodilator
therapy only, whereas those with more severe symptoms and high exacerbation risk warrant additional therapy, e.g. ICS such as budesonide).\textsuperscript{10-11}

Other therapies used in COPD, which have been proven to be beneficial, include LABA and LAMA combinations and phosphodiesterase-4 inhibitors (e.g. roflumilast). Important adjunctive management of COPD patients also includes influenza and pneumococcal vaccine immunisation, which is appropriate for all stages of COPD, and cardiopulmonary rehabilitation. With end stage lung disease, patients are very symptomatic and may require domiciliary oxygen therapy. Lung volume reduction surgery and lung transplantation may also be considered in patients with severe COPD.\textsuperscript{10-11}

1.4 The burden of chronic obstructive airway disease in developing countries

The prescription of inhaled therapy is rising in South Africa due to the exponential rise in the incidence of asthma and COPD.\textsuperscript{1} According to a recent report by the GINA, South Africa has the world’s 4\textsuperscript{th} highest asthma death rate among 5 to 35 year-olds. It is estimated that 1.5% of the 3.9 million South Africans with asthma, die of this condition annually.\textsuperscript{2-3, 12}

The latest World Health Organisation (WHO) statistics in 2005 confirmed that approximately 5% of all deaths globally are estimated to be due to COPD.\textsuperscript{12-13} This correlates to 3 million deaths annually. The majority of the deaths (90%) are thought to occur in low and middle income countries such as South Africa. According to the WHO Global Burden Disease Project, COPD will be the 3\textsuperscript{rd} leading cause of death globally by 2030, and will surpass HIV/AIDS in Africa.\textsuperscript{12-13}
Health services in low-resource countries are poorly adapted to treating chronic diseases.\cite{14} The absence of efficient infrastructure in many countries, and the high cost of drugs in low-resource regions mean that many people have limited access to effective treatment.\cite{14} These factors impact negatively on the overall management of patients requiring inhaled therapy. Upgrading equipment in hospitals, purchasing effective high-quality drugs at low prices, routine training and supervision of health services personnel, and constantly evaluating the performance of HCPs are key to positively changing the trajectory of the predicted high mortality and morbidity of asthma and COPD.\cite{15}

\subsection*{1.5 Disease control and principles of management}

Inhaled bronchodilators and corticosteroids, most commonly administered by MDIs are crucial to the management of both asthma and COPD.\cite{16} When used correctly, they have been shown to provide symptomatic relief, prevent acute exacerbations and improve lung function in COPD.\cite{17} In asthma, effective treatment prevents permanent airway obstruction and airway hyper-responsiveness.\cite{18}

MDIs are the most common inhaler devices used for delivery of inhaled therapy globally.\cite{16} They deliver a specific amount of medication, stored in a highly pressurized canister to the lungs, in the form of a short burst of aerosolized medicine, self-administered by the patient via inhalation. They are, however, technically more difficult to use compared to dry powder inhalers, as they require good simultaneous coordination between the handling of the device, and respiration. Patients are therefore more prone to make a critical error, when compared to patients using less technically difficult inhaler devices.\cite{17} Uncontrolled asthma and COPD are frequent causes of emergency department visits and hospital admissions.\cite{18} Adherence alone is not sufficient unless MDIs are used
Improper inhaler technique translates to uncontrolled airway disease, increased visits to the emergency department and increased hospital admissions.\textsuperscript{19} Research has shown that unless patients receive clear instruction, including a physical demonstration on the specific type of inhaler they are using, they are unlikely to use them correctly.\textsuperscript{20} No inhaler should ever be prescribed without providing education on its correct use. A study in the UK by Hardwell \textit{et al.}\textsuperscript{21} showed that 85.6\% of 1291 asthmatic patients using MDIs failed their first attempt on demonstrating their inhaler technique.

Inhaler technique should be assessed at every visit when symptom control is being assessed.\textsuperscript{20} Repeated demonstrations, observation of the patients’ technique, and reinforcement of proper inhaler technique are essential.\textsuperscript{22} Research shows that many patients do not receive regular counselling or physical demonstration of correct inhaler technique.\textsuperscript{17} A study in Zurich by Steurer-Stey \textit{et al.}\textsuperscript{23} showed that only 32\% of general physicians felt that they should be educating patients, whilst the remaining 68\% felt that education should be done only at a pulmonologist specialist centre. Physicians prescribing inhaler therapy have been shown to have poor compliance with regard to checking and observing patients' inhaler technique.\textsuperscript{24}

Optimal control of asthma and COPD largely depends on the correct use of inhaler devices. However, HCPs have been shown to lack basic knowledge and skill in the use of MDIs.\textsuperscript{25-26} Another study revealed that only 14.2\% of physicians could demonstrate MDI technique correctly.\textsuperscript{27} HCPs and medical students do not regularly receive formal training in the use of inhaler devices.\textsuperscript{27} Findings in these studies highlight the need for regular education programmes for all undergraduate medical students, as well as all nurses and physicians.\textsuperscript{24}
1. 6 Patients MDI technique and the role of HCPs

A study by Pothirat et al.\textsuperscript{28} assessed the use of a much easier to use hand-held dry powder device (Handi-Haler\textsuperscript{®}), vs. a MDI. The study showed that patients using this device had the lowest compliance failure (42.5%). These devices are unfortunately less accessible to the South African public health sector due to higher cost. The study emphasised that "face-to-face" inhalation technique training significantly increased technique compliance for the MDI.\textsuperscript{28}

Erickson et al.\textsuperscript{29} studied a total of 159 patients, directly observing their MDI technique. This study showed that more than 82% of patients exhibited inadequate technique (more than 2 out of 6 steps incorrect). Another study showed that although the majority of the patients claimed to know how to use inhaler devices, 94.2% committed at least one error in the demonstration of their technique.\textsuperscript{30} This suggests discordance between understanding and practice. Therefore, it is not sufficient to verbally assess patients' knowledge on the use of inhaler devices. Physical demonstrations and direct observation of inhaler technique should be mandatory in order to minimize errors and optimize treatment effect.\textsuperscript{30}

1. 7 Patient factors preventing correct MDI technique and the role of HCPs

Low education level was the single most important factor related to incorrect technique as demonstrated by the study done by Pothirat et al.\textsuperscript{28} (adjusted odds ratio 4.1; 95% CI 1.2–13.4, p=0.022). With formal training of the patients studied, there was a statistically significant decrease in the percentage of incorrect techniques for all devices, including MDIs. Individualised training on inhaler technique education, is necessary for all patients, especially in patients with low education levels.\textsuperscript{28}
HCPs working in the public health sector should be sensitised to the socio-economic and educational levels of the patients served. Greater efforts should be made to ensure patients are taught correct use of MDIs.

Therefore, this study was conducted to evaluate the knowledge of MDI technique by HCPs and final year medical students in Gauteng, South Africa at Chris Hani Baragwanath Academic Hospital (CHBAH) and Helen Joseph Hospital (HJH). We also aimed to assess the level of compliance by HCPs in checking and demonstrating MDI technique for patients on inhaled therapy.

1.8 Study objectives

1. To evaluate the HCPs and medical students’ level of knowledge and understanding of MDI technique.
2. To assess the HCPs and medical students’ inhaler technique via a placebo inhaler.
3. To determine the study participants' perceptions on educating patients on inhaler technique and determining whether they routinely check their patients’ inhaler technique at every visit.

1.9 Methods

The study sample comprised of medical doctors of all ranks, nurses and final year medical students at two tertiary hospitals, HJH and CHBAH. The HCPs interviewed were those prescribing MDIs in their respective departments, i.e. Department of Accident and Emergency Medicine, Department of Internal Medicine and Division of Pulmonology.
The study was piloted by inviting target study participants to volunteer to partake in the study via an announcement email and formal letter, via the Medical School Student council, all Heads of department, Heads of hospitals, and the University of Witwatersrand's student coordinator. This recruitment email and letter detailed the background and the objectives of the study, and provided pertinent information regarding them as potential study participants. Those who voluntarily offered to take part in the study were interviewed. Interviews were conducted over a three month period from June 2015 till September 2015, during and after working hours in the various medical wards and emergency department areas in the abovementioned hospitals.

1. 9.1 Study Sample

The sample size for the study comprised 195 study participants. It was calculated using the following standardised formula:

\[ n = \frac{z^2 p (1-p)}{\delta^2} \]

Sample size

\( p = \text{proportional to outcome} (0.15) (10 < p < 15) \)

\( z = 95\% \text{ CI} (1.96) \)

\( \delta = \text{error allowed} (0.05 = \text{only 5\% error allowed}) \)

According to the University of Witwatersrand's Student Administration department, there were 184 final year medical students rotating through the Departments of Internal Medicine and Emergency Medicine at the time of the data collection. The Human Resource Departments of both CHBAH and HJH had in their employment 111 medical registrars, 63 interns, 2 medical officers and over 100 nurses in the Departments of Internal Medicine and the Divisions of Pulmonology; and a total of 7 registrars, 16 interns and 38 medical officers in the Department of Emergency Medicine.
In summary, of the 195 study participants interviewed, 49% (n=96) were medical doctors, 32% (n=62) were final year medical students and 19% (n=37) were nurses. The proportions of the study sample allocated to the different categories of participants reflect the recommended proportions as calculated by our sample size formula. Consenting HCPs and final year medical students were interviewed during and after working hours at the medical emergency department, Pulmonology outpatient department and the medical wards at CHBAH and HJH.

1.9.2 Data Collection

Data for this study was collected prospectively over three months from June 2015 till September 2015, by administering a questionnaire to the study participants, gauging their perceptions, level of knowledge and understanding of MDI technique. Study participants were then requested to demonstrate the correct inhaler technique via a placebo inhaler device.

Correct inhaler technique involves 6 manoeuvres in the following sequence: (1) Shaking the canister, (2) Exhaling to residual volume, (3) Coordinated simultaneous activation of the MDI with initiation of inspiration, (4) Inhaling through the mouth, (5) Slow deep inhalation over 5-6 Seconds, (6) Holding of breath for at least 5 seconds prior to exhalation. Each of the 6 manoeuvres required for correct MDI technique was allocated 1 point. The total for each participant was calculated. The investigator was the sole observer for the study. Sterility and good hygiene practice was maintained whilst using the placebo inhaler devices. All collected data was entered into an Excel database.

The following analyses were computed:
1. Proportion of medical students who had been taught inhaler technique.

2. Proportion of HCPs taught inhaler technique as undergraduates at a teaching institution vs. those taught only once fully qualified as medical practitioners.

3. Proportion of participants who regularly educate their patients on inhaler technique and check inhaler technique at every visit.

4. Proportion of study participants able to perform the MDI technique correctly, demonstrating all 6 manoeuvres in sequence vs. those unable to do so. Since each manoeuvre is important in adequate delivery of inhaled medication, any component incorrectly performed was regarded as a critical error. The proportion of participants performing a critical error for each of the 6 manoeuvres was calculated.

1. 9.3 Statistical analysis

Categorical data was analysed using STATA 10.1 statistics software package (StataCorp, Collage Station, TX), utilizing Fisher's exact test and, in some cases, the Chi Square test. Fisher's exact test was favoured for our small sample.

1. 10 Limitations

The participants interviewed were based in the Public Health Sector only.

1. 11 Ethics

The study was granted ethics clearance on the 27th September 2013 by the Human Research Ethics Committee (Medical) (clearance certificate number M130910).
### 1.12 Schedule

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### 1.13 Funding

No funding was required.
1.14 References


CHAPTER 2: SUBMISSIBLE ARTICLE

TITLE: EVALUATION OF THE KNOWLEDGE AND CORRECT USE OF METERED DOSE INHALERS BY HEALTH CARE PROFESSIONALS AND MEDICAL STUDENTS IN GAUTENG.

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Short Title: Knowledge and correct use of MDIs by Health Care Practitioners in Gauteng

Conflict of Interest: Nil

Keywords: metered dose inhaler (MDI) technique, Health care professionals, Gauteng
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ABSTRACT

Background

Uncontrolled asthma and chronic obstructive pulmonary disease (COPD) are frequent causes of emergency department visits and hospital admissions. Poor metered dose inhaler (MDI) technique is likely a major contributory cause.

Objectives

This study evaluated study participants' knowledge of MDI technique, and their compliance in checking and demonstrating MDI use, to patients prescribed inhaled therapy.

Methods

A questionnaire was administered to doctors, nurses, and final year medical students at Helen Joseph Hospital and Chris Hani Baragwanath Academic Hospital in the Departments of Internal Medicine, Emergency Medicine and Pulmonology. Participants’ use of a placebo MDI was also evaluated by a scoring system.

Results

The total sample of 195 participants comprised 130 (67%) females and 65 (33%) males. Of these, 133 (68%) were qualified medical staff, and 62 were final year medical students. Only 32 (16%) had adequate MDI technique. Over 50% of participants did not demonstrate MDI technique to patients, or check their patients' technique.
Conclusion

Health care professionals (HCPs) and final year medical students have poor knowledge of inhaler technique and are ill-prepared to teach patients. Also of concern is that the majority do not routinely demonstrate or observe patients’ inhaler technique.
INTRODUCTION

The prevalence of chronic lung disease is increasing in all parts of the globe. Three hundred million people have asthma and 210 million people have chronic obstructive pulmonary disease (COPD) worldwide.\(^1\)\(^-\)\(^2\) The prescription of inhaled therapy is rising in South Africa. The Global Initiative for Asthma (GINA), estimates that South Africa has over 3.9 million asthma sufferers, of which 1.5% die of the condition annually. South Africa has the world’s fourth highest asthma death rate among five to 35 year-olds.\(^2\)\(^-\)\(^4\)

The latest World Health Organisation (WHO) statistics in 2005 confirmed that approximately 5% of all deaths globally are due to COPD.\(^4\)\(^-\)\(^5\) Ninety percent of these deaths are thought to occur in low and middle income countries such as South Africa. COPD will be the third leading cause of death globally by 2030, and will surpass HIV/AIDS in Africa.\(^4\)\(^-\)\(^5\)

Inhaled therapy for chronic airway diseases (bronchodilators and corticosteroids), are most commonly administered by metered dose inhalers (MDIs). They are crucial to the management of both asthma and COPD. MDIs deliver a specific amount of medication, stored in a highly pressurized canister to the lungs, in the form of a short burst of aerosolized medicine, self-administered by the patient via inhalation. When used correctly with adequate dosing, they have been shown to provide symptomatic relief, improve lung function and reduce exacerbations.\(^2\)\(^-\)\(^4\) MDIs however, are technically more difficult to use compared to dry powder inhalers, as they require good simultaneous coordination between the handling of the device, and respiration. Patients are therefore more prone to make a critical error, when compared to patients using less technically difficult inhaler devices.\(^6\)
Research shows that many patients do not receive regular counselling or physical demonstration of correct inhaler technique.\textsuperscript{6} Physicians have been shown to have poor compliance with checking and demonstrating MDI use to patients prescribed inhaled therapy.\textsuperscript{7}

This study was conducted to evaluate the knowledge of MDI technique by healthcare professionals (HCPs) and final year medical students, as well as their compliance in checking and demonstrating MDI technique for patients on inhaled therapy. The burden of asthma and COPD is on the rise in South Africa, and greater efforts should be made to ensure patients are taught correct use of MDIs, and that full compliance to treatment guidelines by HCPs is practised.

\textbf{MATERIALS AND METHODS}

\textbf{Study population and data collection}

This was a prospective study of HCPs comprising medical doctors and nurses in varying ranks, as well as final year medical students working in the Departments of Internal Medicine and Emergency Medicine, and the Division of Pulmonology at Helen Joseph Hospital (HJH) and Chris Hani Baragwanath Academic Hospital (CHBAH).

A total of 195 study participants volunteered to take part in the study. A questionnaire was administered to the study participants gauging their perceptions, level of knowledge and understanding of MDI technique. They were then requested to demonstrate correct inhaler technique via a placebo MDI. Correct inhaler technique involves 6 manoeuvres in the following sequence: (1) Shaking the canister, (2) Exhaling to residual volume, (3) Coordinated simultaneous activation of the MDI with initiation of inspiration, (4) Inhaling through the mouth, (5) Slow deep inhalation over 5-6 Seconds, (6) Holding of breath for at least 5
seconds prior to exhalation. Each of the six manoeuvres required for correct MDI technique demonstrated by the participant was allocated one point. Since each manoeuvre is important in adequate delivery of inhaled medication, any component incorrectly performed was regarded as a critical error. The total for each participant was calculated. All errors were documented.

**Statistical Analysis**

All collected data was entered into an Excel database. The categorical data was analysed using STATA 10.1 statistics software package (StataCorp, Collage Station, TX). Fisher's exact test was used to detect statistically significant associations between knowledge of MDI use by the different study participants and their compliance in checking and demonstrating MDI use to patients.

**RESULTS**

**Demographics**

Most of the study participants interviewed were female (n=130) (Refer to table 1). There was no statistical difference in questionnaire responses or demonstration of MDI technique between males and females (p= 0.2298) (Table 1).

A total of 62 final year medical students studying at the University of Witwatersrand and 133 qualified HCPs were interviewed. A third of the HCPs studied at the University of Witwatersrand, whilst 12% studied outside of South Africa. Only 15(11%) of the total HCP pool had been qualified for more than 10 years (Table 1). Irrespective of their years of experience, rank, or location of undergraduate studies, there was no statistical difference in
adequate knowledge of MDI use, as well as compliance in checking and demonstrating MDI technique to patients.

HCPs and final year medical students' performance of MDI technique:
Only 16% of all study participants were able to perform the technique correctly (Figure 1). There was no difference on the scores between medical students and HCPs on whether they had adequate inhaler technique or not (p=0.5243).

Factors predisposing to poor knowledge of MDI technique:
All HCPs and final year medical students interviewed acknowledged the importance of having good knowledge of MDI technique. They also showed good insight into how correct MDI use significantly impacts disease control and reduction of morbidity and mortality. The study showed that there was no statistical significant difference between final year medical students and qualified HCPs (including nurses), on their knowledge of correct MDI use.

A third of study participants were never taught MDI technique. Of the remainder, nearly 50% of study participants were taught by lecturers at teaching institutions, whilst less than 20% were taught by colleagues (Figure 2). There were no identifiable educational programmes in place dedicated to teaching HCPs on MDI technique and treatment protocols for patients on MDIs. Similarly, there was lack of placebo MDIs in medical wards, emergency and pulmonology outpatient departments.
HCPs compliance in checking patients' MDI technique, as well as demonstrating MDI technique to patients:

Fifty-seven percent of study participants declared never observing patients' MDI technique at every hospital-related visit (Figure 3). Forty percent of study participants admitted to never demonstrating MDI technique to patients (Figure 4). No particular explanations for this were offered by the study participants. There was no statistically significant difference between those who knew and those who did not know the correct MDI technique with regard to whether they demonstrated (p=0.0728) and/or observed their patients’ inhaler technique (p=0.1564) (Table 2).

In this study, 45% of all participants felt the responsibility to teach MDI technique was that of the treating doctor alone, whilst 21% were of the opinion that this was the nurse’s responsibility.

DISCUSSION:

The immense burden of infectious disease in Sub-Saharan Africa has influenced governments to focus their limited recourses on aggressive health campaigns in this area, and neglect non-communicable diseases such as asthma and COPD.

The increasing burden of COPD and asthma in our country is of great concern. Optimal management largely depends on the correct use of inhaler devices by patients, as well as repeated demonstrations and observation of patients' inhaler technique by HCPs.

Inadequate knowledge of MDI use by HCPs has been documented globally with similar findings in our local study. Plaza Vet al\textsuperscript{8} showed that only 14.2% of 1514 physicians studied


had adequate MDI technique. A South-American based study of 239 physicians, showed that only 30% of all participants could demonstrate MDI technique correctly. The same study also demonstrated that 49% of the individuals interviewed in the Pulmonology-Cardiac specialist centre, and 19% of the individuals interviewed at a general Internal Medicine centre were able to perform inhaler technique correctly. They postulated that the large difference between participants in the specialist centre and the general medical centre was due to the increased exposure of patients on inhaler therapy to those working at the specialist centre. 

Our study, with participants predominantly based in the Internal Medicine wards, Emergency and outpatient departments, showed that only 16% of participants had adequate MDI technique. Since only a small percentage of study participants were from the Division of Pulmonology (1.5%), we could not analyze whether there was a statistically significant difference between participants in the specialist unit vs. those in general medicine. However, it is clear that there is overall poor knowledge of MDI use amongst HCPs. Contributing to this was the absence of placebo MDIs for demonstration of MDI technique in medical wards, emergency and pulmonology outpatient departments.

A third of our study participants were never taught MDI technique, with no identifiable educational programmes in place for this purpose. Rebuck et al. were of the opinion that postgraduate teaching programmes with regard to MDI use should be determined by the needs of day-to-day patient care by HCPs. They conducted a study to determine if structured educational intervention vs. none would be sufficient to teach postgraduate physicians inhaler skills that can be sustained over a long period. The 8-month follow up of participants in the intervention group showed great improvement in the knowledge of MDI use compared to their baseline results (59% vs.42%, p<0.05). The intervention group performed better that the control group overall (59% vs. 39%, p<0.05).
Twenty percent of participants in our study were taught by fellow colleagues in an informal vs. a structured teaching environment. The enforcement of structured teaching in the workplace as well as in our teaching institutions will improve knowledge of MDI use. The findings of our study should alert all HCPs, teaching institutions, senior personnel and managers to prioritise teaching MDI technique so that they may educate their patients, and positively impact on disease control. Prioritising teaching MDI technique to HCPs will also sensitise them to the importance of compliance with treatment guidelines.

Plaza et al.\textsuperscript{8} found that only 27.7% of 1514 physicians checked their patients' inhaler technique when inhaled therapy was being prescribed. A study done in Zurich by Steurer-Stey et al.\textsuperscript{11} found that 60% of physicians interviewed checked inhaler technique, and a significant two-thirds of the study participants expressed that patient education should be done at a Pulmonology specialist centre. A survey of patients in a Pulmonology unit in Japan, found that only 17.1% of patients were given repeated physical demonstrations of MDI technique by a respiratory physician.\textsuperscript{12} Our study found that 57% of study participants admitted to never observing patients' MDI technique, whilst 40% admitted to never demonstrating MDI technique to patients. Our study also found that having adequate knowledge of MDI technique did not translate to the participants complying with checking and demonstrating MDI use in real world practice. Also of concern is that this occurred despite the majority of study participants’ view that the treating doctor should be the sole responsible person for educating patients on MDI use. Our study population was much smaller than the above quoted studies, but concurs with their findings. All HCPs involved in the care of patients on inhaled therapy should ensure that they are familiar with correct inhaler technique and undertake the responsibility to educate their patients on MDI use routinely.
This obligation is all the more important as we live in a developing country and therefore have less access to more user-friendly and costly devices. Our patients also have lower education levels and therefore require greater efforts to ensure correct inhaler technique is learnt and sustained.

**LIMITATION:**
Privately practising nurses, general practitioners, specialist physicians, and pulmonologists who see patients using MDIs are not included in this study.

**CONCLUSION:**

Knowledge of correct MDI technique amongst HCPs and final year medical students was poor. The study also revealed poor compliance amongst HCPs in observing patients' inhaler technique and demonstrating correct inhaler technique to patients.

It is our recommendation that all teaching institutions, departments of Internal medicine, emergency medicine and affected outpatient departments should have educational programmes in place dedicated to teaching correct MDI technique to HCPs and patients. It is also our recommendation that HCPs should be familiar with treatment protocols for patients on inhaled therapy.

Placebo inhaler devices should be easily accessible at all hospitals to enable HCPs in demonstrating MDI technique to patients.
### Table 1: Demographics of study participants

<table>
<thead>
<tr>
<th>Demographics</th>
<th>N (%)</th>
<th>Gender</th>
<th>(n=195)</th>
<th>HCP Total (n=133)</th>
<th>HCP Years of Experience* (n=133)</th>
<th>Final Year Medical Students</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Female</td>
<td>130 (67)</td>
<td>Medical Doctors</td>
<td>&gt;10 Years 15 (11.3)</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Males</td>
<td>65 (33)</td>
<td>Nurses</td>
<td>5-10 Years 51 (38.3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;5 Years 67 (50.4)</td>
<td></td>
</tr>
</tbody>
</table>

HCP, Health Care Professional.  
*Number of years post undergraduate qualification.

### Table 2: HCPs MDI technique and their compliance in checking and demonstrating MDI technique to patients on inhaled therapy

<table>
<thead>
<tr>
<th></th>
<th>Adequate MDI Technique: n (%)</th>
<th>Inadequate MDI technique: n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of HCPs</td>
<td>(n=32)</td>
<td>(n=101)</td>
</tr>
<tr>
<td>Male</td>
<td>15 (47)</td>
<td>35 (35)</td>
</tr>
<tr>
<td>Female</td>
<td>17 (53)</td>
<td>66 (65)</td>
</tr>
<tr>
<td>Demonstrates MDI technique</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>8 (25)</td>
<td>72 (71)</td>
</tr>
<tr>
<td>No</td>
<td>24 (75)</td>
<td>29 (29)</td>
</tr>
<tr>
<td>Checks patients’ MDI technique</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (12.5)</td>
<td>53 (52)</td>
</tr>
<tr>
<td>No</td>
<td>28 (87.5)</td>
<td>48 (48)</td>
</tr>
</tbody>
</table>

HCP, Health Care Professional. MDI, Metered Dose Inhaler.
Figure 1: Study participants’ MDI technique via a placebo MDI. (Correct MDI technique refers to all six manoeuvres adequately performed for effective drug delivery).

Figure 2: Participants' MDI technique educator
Figure 3: HCPs' observation of patients' MDI technique

Figure 4: Demonstration of MDI technique to patients by HCPs.
REFERENCES:


CHAPTER 3: APPENDICES

3. 1 Data Collection Sheet

TITLE: EVALUATION OF THE KNOWLEDGE AND CORRECT USE OF METERED DOSE INHALERS BY HEALTH CARE PROFESSIONALS AND MEDICAL STUDENTS IN GAUTENG.

1. Sex
   - Male
   - Female

2. Graduation from Medical School/Nursing College
   - >10 Years ago
   - 5-10 Years ago
   - < 5 Years ago
   - Not applicable

3. Place of Qualification
   - UCT
   - Walter Sisulu University
   - University of Limpopo (Medunsa)
   - Stellenbosch
   - UKZN
   - Wits
   - UP
   - Other: ____________
4. Department of work
   o Emergency Medicine/Casualty
   o Internal Medicine Department
   o Pulmonology Department

5. Current Rank
   o GEMP 3/GEMP 4
   o Intern
   o Medical Officer
   o Registrar
   o Nurse: (Rank)_________________

6. Were you ever taught the correct technique for using a metered dose inhaler?
   o YES
   o NO

7. By who were you taught technique? (Only answer if your answer to number "7" is "YES")
   o Lecturer at University/Medical School
   o Taught at work by a colleague in the same rank as me
   o Taught at work by a colleague in a higher rank than myself.
   o Taught at work by a colleague in a lower rank by myself

8. Have you managed a patient prescribed a Metered Dose Inhaler?
   o YES
   o NO

9. When managing a patient on a Metered Dose Inhaler, do you observe the patient’s inhaler technique?
   o Yes, at every visit.
10. When managing a patient on a metered dose inhaler, have you physically demonstrated the correct MDI technique, to the patient?
- Yes, at every visit
- Yes, more than once every 3 months
- Yes, less than once every 3 months
- No

11. Who do you think is the best person to educate the patient on inhaler technique?
- The treating medical doctor
- The pharmacist
- The nurse

**Assessment of the participants' inhaler technique:**

A. Shaking the canister: YES/NO

B. Exhaling to residual volume: YES/NO

C. Coordinated simultaneous activation of the MDI with initiation of inspiration: YES / NO

D. Inhaling through the mouth: YES/NO

E. Slow deep inhalation over 5-6 Seconds: YES/NO

F. Holding of breath for at least 5 seconds prior to exhalation: YES/NO
1. Was the participant able to perform all six manoeuvres correctly?
   - Yes
   - No

2. How many manoeuvres did the participant perform correctly?
   - 1
   - 2
   - 3
   - 4
   - 5
   - 6
3.2 Ethics Clearance Certificate

R14/49 Dr Hlanjwa Maepa

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130910

NAME: (Principal Investigator) Dr Hlanjwa Maepa

DEPARTMENT: Internal Medicine
Chirs Hani Baragwanath Academic Hospital
Helen Joseph Hospital, Lillian Ngoyi & Zola Clinics

PROJECT TITLE: Evaluation of the Knowledge and Correct use of Metered Dose Inhalers by Health Care Professionals and Medical Students in Gauteng

DATE CONSIDERED: 27/09/2013
DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Prof Michelle Wong & Dr Colin Menezes

APPROVED BY: Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 30/10/2013

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and ONE COPY returned to the Secretary in Room 10004, 10th floor, Senate House, University. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. I agree to submit a yearly progress report.

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES