

THE CATHOLIC UNIVERSITY OF AMERICA

Asthma Clinical Practice Guideline Implementation and Evaluation in a Military  
Treatment Facility Pediatric Clinic

AN EVIDENCE-BASED PRACTICE PROJECT

Submitted to the Faculty of the

School of Nursing

In Partial Fulfillment of the Requirements

For the Degree

Doctor of Nursing Practice

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By

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# Asthma Clinical Practice Guideline Implementation and Evaluation in a Military

## Treatment Facility Pediatric Clinic

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Asthma is a common chronic disease of childhood, affecting more than six million children (NHLBI, 2007). Several national guidelines regarding asthma diagnosis and treatment are available. Two of the most accepted are the National Heart, Lung, Blood Institute (2007) and the Department of Defense and Veteran's Affairs (DoD/VA, 2009) clinical practice guideline (CPG). These guidelines assist Health Care Providers (HCP's) in delivering the most current and accepted standards of practice for patients with asthma. However, compliance is often difficult for HCPs as well as patients.

The purpose of this evidence-based project was to implement the DoD/VA asthma CPG at a Military Treatment Facility pediatric clinic. Compliance with the asthma CPG was evaluated in 5 specific areas: emergency department visits, acute care visits, hospitalization rate, use of a written asthma action plan and prescription of inhaled corticosteroid for any severity of persistent asthma.

The Stetler Model of Research Utilization (2001) was used to facilitate this project. After literature review and an organizational assessment, this author utilized a combined approach of provider education and extrinsic tools to implement the CPG. A 3-month retrospective chart review was completed prior to and three months after CPG implementation. The two groups had similar ages, sex, and sponsor status. Following implementation of the CPG, there was a 6% decrease in the percentage of ED visits. However, there was a slight increase in rates of acute care visits and hospitalizations (2% and 6%, respectively). A small (2%) increase was also noted in the use of ICS. Unfortunately, post-CPG implementation data collection coincided with the winter months, which may have been a confounder. There was a larger increase in use of written asthma action plan post-CPG implementation (14 to 44%). Using the z-test of proportions, only the increase in the use of asthma action plan was statistically significant.

Although there was not significant improvement in the majority of outcomes measured, the primary goal of this project was implementation of the asthma CPG. No one method of CPG implementation has been proven to be more successful than another method according to the literature. Through the process of this evidence-based practice project, Providers have voiced an increased awareness of the DoD/VA CPG. Although not formally measured, this provides a basis for future in depth study and analysis. This project will be sustained via ongoing process improvement monitoring and reporting.

This evidence-based project by Jane E. Jacknewitz-Woolard fulfills the requirements for the doctoral degree in Doctor of Nursing Practice approved by Janice G. Agazio, PhD, CRNP as Director, and by Elizabeth Hawkins-Walsh, PhD, CRNP, and Andrew J. Lipton, MD, as readers.

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## Dedication

This project would not have been possible without the support of my colleagues and friends at Walter Reed Army Medical Center. A special 'thank you' to COL (Dr.) Andy Lipton, who selflessly helped me complete this project even as he deployed to Afghanistan. He is the epitome of the Army values of 'selfless service' and 'dedication to duty'.

I would not have completed this program if not for Vicki Long, my guide and touchstone from the first day. I am indebted to Mary Elwood who patiently provided knowledge and expertise in the completion of this manuscript. A special acknowledgement to my mentor, LTC (Ret) Teri Reid, who taught me how to care for children and their families.

Finally, my husband, Jud, and children, Cecilia, Jackson, and Savannah. Thank you for understanding.

TABLE OF CONTENTS	Page
DEDICATION . . . . .	iii
LIST OF TABLES . . . . .	vi
LIST OF APPENDICES . . . . .	vii
CHAPTER	
I. NATURE AND SCOPE OF THE PROJECT	
Introduction. . . . .	1
Scope of the Problem . . . . .	2
Significance . . . . .	3
Project Objectives . . . . .	5
II. SYNTHESIS AND ANALYSIS OF SUPPORTING AND RELATED LITERATURE	
Methodology of Literature Review . . . . .	6
Review of the Literature Findings . . . . .	7
Conclusion . . . . .	13
III. PROJECT METHODS	
Research Model . . . . .	15
Organizational Context and Considerations . . . . .	17
Outcomes to be Measured . . . . .	20
Method for Data Collection . . . . .	21
Human Subjects Considerations . . . . .	21
Sustainability . . . . .	22
Relevance to Nursing . . . . .	22
IV. PROJECT IMPLEMENTATION	
Introduction . . . . .	24
Process Application . . . . .	25
Conclusion . . . . .	32
V. RESULTS, EVALUATION, IMPLICATIAONS AND CONCLUSIONS	
Results . . . . .	34
Evaluation . . . . .	38
Implications . . . . .	41
Conclusions . . . . .	44
APPENDICES . . . . .	47
REFERENCES. . . . .	68

## LIST OF TABLES

Table	Page
1. Anticipated Cost Savings .....	13
2. Provider Education .....	23
3. Baseline Data .....	27
4. Comparison of Groups Pre/Post Implementation .....	34
5. Pre-implementation Data .....	36
6. Post-implementation Data .....	37
7. Statistical Results .....	38

## LIST OF APPENDICES

Appendix	Page
A. Assessment of Severity. . . . .	47
B. Asthma Control . . . . .	49
C. Stepwise Guide to Medication Management . . . . .	51
D. Asthma Action Plan . . . . .	53
E. Asthma Control Test . . . . .	55
F. Waiting Room Posters . . . . .	57
G. Patient Education Booklet . . . . .	59
H. Valved Holding Chamber Education . . . . .	61
I. Letter of Approval to Conduct Study, Walter Reed Army Medical Center . . . . .	64.
J. Exemption Certificate, The Catholic University of America, Committee for the Protection of Human Subjects . . . . .	66

## CHAPTER ONE: NATURE AND SCOPE OF THE PROJECT

### **Introduction**

Asthma is one of the most common chronic diseases of childhood, affecting more than six million children (NHLBI, 2007). There are currently several national guidelines regarding asthma diagnosis and treatment. Two of the most accepted are the National Heart, Lung, Blood Institute (NHLBI) published in 2007 and the Department of Defense and Veteran's Affairs (DoD/VA) clinical practice guideline (CPG), published in December 2009. The Global Initiative for Asthma (GINA), American College of Chest Physicians (ACCP), and American Academy of Allergy, Asthma and Immunology (AAAAI) are also utilized by various Health Care Providers (GINA, 2009; ACCP, 2006; AAAAI, 2005). These national guidelines assist Health Care Providers (HCP's) in delivering the most current and accepted standards of practice for asthmatic patients, however, compliance is often difficult for HCP's as well as patients. Low compliance rates have led to less than optimal patient outcomes and have been implicated in lower quality of life for asthmatic patients (NHLBI, 2007; Newcomb, 2006). This Evidence-Based Practice (EBP) project involves implementing and evaluating the DoD/VA asthma CPG in a Military Treatment Facility (MTF) pediatric clinic. The project will also include the necessary process to ensure continued sustainability and compliance with the CPG.

### **Problem Identification**

The NHLBI Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma is a massive, 440-page evidence-based guideline covering all aspects of pediatric and adult asthma identification, diagnosis, treatment and management. The current



DoD/VA asthma CPG is over 150 pages with a summary alone of 77 pages. As was the case with previous CPGs, busy primary care or emergency room departments found the salient points of these extensive guidelines difficult to identify with and follow. Provider compliance rates have been estimated as low as 45% (Swartz, Banasiak, & Meadows-Oliver, 2005) and parent and/or patient compliance rates have been as low as 15% in some studies (Gustafsson, Watson, Davis, & Rabe, 2006). The low compliance rates have led to less than optimal patient outcomes and have been implicated in lower quality of life for asthmatic patients (NHLBI, 2007; Newcomb, 2006). In addition, the indirect costs to families cannot be underestimated: school absenteeism, missed work by parents or caregivers, and emergency room visits, all of which significantly impact patients and families.

Clinicians are increasingly expected to practice evidence-based medicine, but they must be given the tools necessary to practice those guidelines. Research shows that when guidelines are adhered to, there can be a dramatic improvement in the quality of life for asthmatic patients. (Boychuk, 2006; Lesho, Myers, Ott, Winslow & Brown, 2005; Newcomb, 2006).

This author currently works as a Pediatric Nurse Practitioner in the Pediatric Pulmonology Service at a major military treatment facility (MTF). Anecdotally, many patients are referred to the Pulmonology service whose asthma management is not consistent with current guidelines. A discussion with pediatric clinic staff confirmed that previous asthma CPGs were never formally introduced or implemented within the clinic.

## **Project Significance**

Asthma is a chronic lung disease characterized by airway inflammation and reversible airway obstruction. It is a significant public health problem in the United States affecting over 22 million people, including more than 6 million children (CDC, 2007, NHLBI, 2007). The Centers for Disease Control and Prevention (2007) note that current asthma prevalence is higher in children (8.5%) as compared with adults (6.7%) and higher in females (8.1%) as compared with males (6.2%). There continue to be distinct variances among racial and ethnic groups with blacks (9.2%) and Latinos of Puerto Rican descent (14.5%) having higher rates compared with whites (6.9%) or Latinos of Mexican descent (3.9%) (CDC, 2007).

While there may be some genetic component related to the ethnic disparities, studies suggest that adherence to therapy, access to care, plus environmental and psychosocial factors play a larger role in the documented differences of prevalence and morbidity (DoD/VA, 2009; Strine, et al, 2008; NHLBI, 2007; Swartz, 2005). Additionally, while the overall asthma mortality rates declined from 1980 to 1999, some of this decline may have been attributable to changes in coding documentation (CDC, 2007). Since 2000 there has been a steady increase in the mortality rate (CDC, 2002; NHLBI, 2007). In 2004, a total of 186 deaths among children less than 18 years of age were attributed to asthma – a rate of 0.4 deaths per 10,000 children with asthma compared with 2.9 deaths per 10,000 adults (>18 years of age) with asthma (CDC, 2007). Asthma mortality continues to be higher in blacks and Hispanics compared with whites (CDC, 2007; NHLBI, 2007).

Asthma also accounts for significant monetary burden on patients and society. In 2004, the direct costs of asthma were estimated to be \$11.5 billion (NHLBI, 2007). The cost of

medication, which can run as high as \$400 per month, accounted for the largest portion of this figure (AHRQ, 2007). In 2004, there were 198,000 hospitalizations for pediatric asthma, which also significantly impacted the direct cost of asthma care. Indirect costs, such as missed school or work, or decreased quality of life, are not factored into this amount.

The Agency for Healthcare Research and Quality (AHRQ) has baseline data regarding medical care utilization for pediatric patients with asthma. The average cost for a hospitalization in 2007 was \$5851.00. For an emergency department visit, the cost was \$313.00 and for an acute care visit, the cost was \$88.00. These costs were utilized to estimate cost-effectiveness of the intervention.

Successful implementation of the asthma CPG should decrease direct costs to the MTF. One significant advantage that the military health care system offers in contrast to the civilian healthcare system is that cost and the access to specialty care is rarely a barrier to patients. Prescriptions filled at a MTF are free, as are emergency department and acute care appointments. Inpatient hospitalization is also free for family members of Active Duty service members and only \$15.65 per day for Retiree family members. However, the indirect costs, of missed school (work for parents), commute to the MTF, family stress due to acute care visits or hospitalizations, are a concern, but unfortunately, difficult to calculate monetarily and beyond the scope of this project.

Although the military healthcare system, in particular, Walter Reed Army Medical Center (WRAMC), does not routinely perform cost-benefit or cost-effectiveness studies, the effectiveness of an intervention should be measured for the benefit of the patient. In addition, HCPs have a limited amount of time with patients, therefore the most efficient

and effective method of health promotion with regards to HCP time and resources should be measured and initiated.

Successful implementation of CPGs has been shown to improve outcomes in numerous studies (O’Laughlen, Hollen & Ting, 2009; Boulet, 2008; To, 2008; NHLBI, 2007; Mangione-Smith, 2005). Few studies, however, have specifically examined the cost-effectiveness of CPG implementation. Limited research does support the cost-effectiveness of CPG implementation in selected patient populations (IOM, 2004; Jans, 2001). It is incumbent on the DNP, as a healthcare leader, to be a facilitator and change agent. A mechanism of sustained process improvement is required to ensure pediatric patients at WRAMC continue to receive the most current, evidence-based care available.

### **Project Objectives**

The goal of this evidence-based project is to effectively implement the DoD/VA CPG in a MTF general pediatric clinic. Key interventions that have been recommended in the CPGs and have been shown to enhance patient outcomes will be improved:

1. Increased use of written asthma action plan
2. Increased prescription of inhaled corticosteroid for any severity of persistent asthma

It is anticipated that adherence to the above interventions will improve patient outcomes in three specific areas:

3. Decreased Emergency Department visits
4. Decreased Acute Care visits
5. Decreased hospitalization rates

## CHAPTER TWO: SYNTHESIS AND ANALYSIS OF SUPPORTING LITERATURE

### **Methodology of Literature Review**

A literature search was conducted via the electronic resources of MEDLINE, ProQuest and Pub Med. Applicable key words or phrases such as: “pediatric asthma”, “clinical practice guidelines”, “implementation”, “asthma outcomes”, “changing provider behavior” were utilized to identify relevant research studies. Studies from 2002 to 2009, inclusive, were obtained for review. The reviewed studies encompassed a myriad of ways to improve asthma outcomes: use of a new asthma assessment tool, increased use of Pediatric Nurse Practitioners or staff nurses, community action programs, and traditional utilization of CPGs. The majority of articles identified various aspects of patient education to be significant for optimal asthma care.

Numerous articles were reviewed that had specific information regarding techniques to implement CPGs. Unfortunately, no one definitive technique was determined to be optimal to CPG implementation success. Implementation techniques ranged from qualitative studies exploring HCPs attitudes regarding CPG use and determining ease of use (Moffat, et al, 2007; Grol & Grimshaw, 2005), to more directive suggestions such as educational training sessions, medical record revisions, CPG format and provider prompting tools (Doherty, et al, 2007; Hartman & O’Connor, 2009; Stone, Schweikhart, Mantese & Sonnad, 2005; Halterman, et al, 2006; O’Laughlen, et al, 2009).

## **Review of the Literature Findings**

Over forty articles were reviewed in preparation for the CPG implementation. The articles were divided into three general themes: 1) information on current CPG use, 2) techniques for CPG implementation and 3) evaluation of outcomes post-CPG implementation. Some articles contained two themes, for example: information about current CPG use as well as tips for implementing CPG in practice (Grol & Grimshaw, 2005; Moffat, CleLand, van der Molen & Price, 2007) or current CPG use and post-CPG evaluation but no specific information on precisely how the CPG was implemented (Borgmeyer, Gyr, Jamerson & Henry, 2008; Cabana, Slish, Nan & Clark, 2004; Newcomb, 2006). The majority of articles reviewed (n=23) had some information regarding evaluation of various clinical outcomes after utilizing CPGs. Additional studies were analyzed to determine the cost-effectiveness of asthma CPG implementation.

**Current Clinical Practice Guideline Use.** The intent of CPGs are to decrease variance in practice by providing evidence-based recommendations to assist Health Care Providers in establishing the most effective treatment plan for their patients. The current NHLBI and DoD/VA CPGs are similar in many areas, as noted below.

1. The assessment of both “impairment” and “risk” are important when determining the severity level of newly diagnosed asthmatics. Appendix A provides information to assess when determining the level of severity and initial medication treatment plan. Determining severity is important as it guides the initiation of treatment.

2. The determination of whether a patient's asthma is well-controlled or not also includes the domains of "impairment" and "risk" and should be routinely assessed. (Appendix B)
3. The use of spirometry on all patients 5 years of age and older suspected of having asthma.
4. Use of inhaled corticosteroids are recommended for all patients with persistent asthma, regardless of severity level.
5. Recommendations for "step up" of medication as well as need for referral for patients whose asthma is not well controlled. See Appendix C for a stepwise guide to treatment of asthma.
6. Assessment and treatment of other comorbid or confounding conditions (eg: allergic rhinitis, obesity, vocal cord dysfunction).
7. The use of written asthma action plans for all patients.

There are some differences in the CPGs, however.

1. The NHLBI utilizes three age categories for patients, 0-4 years, 5- 11 years, and 12 years to adult. As there was very little difference between recommendations for the 5 to 11 and 12 to adult patient groups, the DoD/VA CPG utilizes only two age groups: 0 to 4 ("child") and 5 to adult.
2. The NHLBI also utilizes three categories for assessment of control i.e. "well-controlled", "not well-controlled", and "very poorly controlled". Again, for ease of use, the DoD/VA suggests the patient is either "controlled" or "not controlled".

3. The DoD/VA CPG has recommendations related specifically to Active Duty military personnel.

The current asthma guidelines stress patient education as a significant goal for optimal asthma care. A key component of this goal is the recommendation for written asthma action plans to assist patients in managing their asthma. A written asthma action plan has been shown to improve asthma control and outcomes (NHLBI, 2007; Zemek, Bhogal & Ducharme, 2008). Unfortunately, studies have shown compliance rates with this simple written tool range from 16% (Doherty, et al. 2007) to 44% (McMullen, et al. 2007). Teaching patients how to manage their care is a key role for Nurse Practitioners and, obviously compliance with the asthma action plan needs to be improved. Another area of asthma care that demonstrated a wide variation was the use of metered-dose inhalers and spacers for medication administration with a range as low as 5% (Doherty, et al, 2007) to a high of 81% (McMullen, et al, 2007). The DoD/VA CPG recommends all patients utilize MDIs with spacers for medication administration (DoD/VA, 2009) so this is another area that will need to be monitored at the MTF.

**Techniques for Implementation.** Sixteen articles had information regarding techniques to implement CPGs. Unfortunately, there was not one definitive technique that was determined to be optimal to CPG implementation success. Two articles (Grol & Grimshaw, 2005; Moffat, et al, 2007) explored Health Care Provider's attitudes regarding CPG use and determined that ease of use and organizational issues (training, teamwork) contributed to CPG success. Other studies offered more directive suggestions such as educational training sessions, medical record revisions, CPG format and provider



prompting tools (Doherty, et al, 2007; Halterman, et al, 2006; Stone, Schweikhart, Mantese & Sonnad, 2005).

Most authors focused on Provider-specific versus patient-directed care. Cabana, et al (2006) evaluated the effectiveness of a continuing education program for physicians. The interactive seminar focused, not just on asthma treatment, but also physician communication and patient education skills. Compared to the control group (no physician education seminar), patients who received care from the intervention group reported improved satisfaction with physician communication and experienced a greater decrease in days limited by asthma symptoms and fewer ED visits. To, et al (2008) also evaluated an interactive training workshop for clinic personnel prior to implementing an asthma care program in 15 primary care clinics. Those clinics that participated in the training demonstrated improved outcomes (decreased asthma exacerbations, ED visits, and school absenteeism) compared to control clinics.

The key factor in all of those studies, however, was the use of interactive, educational sessions that are tailored to the Provider's needs and clinical situations (Brown, et al, 2004; Cabana, et al, 2006; Mangione-Smith, et al, 2005).

These concrete approaches may help to guide CPG implementation, but the actual techniques used will depend on the organizational assessment to determine which technique(s) would be optimal in the WRAMC pediatric clinic.

**Outcomes Evaluation.** Several articles dealt either fully, or in part, with evaluation of patient outcomes due to CPG utilization. Unfortunately, the same clinical outcomes were not measured in each of the fourteen studies. Some studies focused on more acute issues such as decreasing emergency department visits or hospitalizations (Coffman, et al 2008;

Lesho, Myers, Ott, Winslow & Brown, 2005; Newcomb, 2006; To, Cicutto, Degani, McLimont & Seyene, 2008), ; Newcomb, 2006;), while others focused on more subjective measures such as patient satisfaction or perception of control (Cabana, et al, 2006; Guevara, Wolfe, Grum & Clark, 2003).

All of the studies documented some short-term (less than 12 month) improvement in the majority of outcomes they studied. Unfortunately, the same clinical outcomes were not measured in each of the studies. Some studies focused on more acute issues such as decreasing emergency department visits or hospitalizations (To, et al, 2008; Newcomb, 2006; Lesho, et al, 2005) while others focused on more patient education measures (Halterman, et al, 2006; Lesho, et al, 2005) or more psychosocial aspects such as patient satisfaction or quality of life (Mangione-Smith, et al, 2005). Only one study (Jans, et al, 2001) showed improvement, but not statistically significant, of lung function and respiratory symptoms. Two studies evaluated outcomes 12 months post-CPG implementation and showed continued improvement in patient outcomes (Doherty, et al, 2007; Mangione-Smith, et al, 2005).

Unfortunately, the literature does not demonstrate one definitive technique as to how to practically implement CPGs in pediatric practices. Nor do these limited studies show evidence of sustained (greater than 12 month) improvement in clinical outcomes. There are a variety of techniques to implement and then evaluate the effectiveness of CPGs in practice. A method of both short-term and long-term evaluation will be necessary to sustain the use of the CPG.

**Cost Effectiveness.** The direct costs to implement the CPG at the MTF will be negligible. A “toolkit” of posters, patient and provider education material will be distributed by the

DoD/VA. No additional human resources will need to be hired. Therefore, the effectiveness of the intervention will be determined by the measured outcomes (hospitalization, ED and acute care visits) and cost savings extrapolated to the MTF.

A MEDLINE search revealed few articles directly studying the cost-benefit of an asthma clinical practice guideline. There were several studies, however, that analyzed the cost-effectiveness of various asthma management programs, i.e. implementing portions of the asthma CPG such as provider or patient education, routine follow-up or a written asthma action plan.

Kaiser Permanente (2006) showed acute care visits decreased 57% in children enrolled in their asthma management program (similar to the NHLBI CPG). Other studies show that the use of written asthma action plans decreased acute care visits by 27% (Zemek, 2008). Improved patient education and routine follow-up has been shown to decrease the mean number of hospitalizations and ED visits as much as 50% (Newcomb, 2006; Coffman, Cabana, Halpin & Yelin, 2008; Brown, Bratton & Cabana, 2004; To, et al, 2008).

AHRQ estimates that pediatric patients enrolled in an asthma management program would experience a 51% decrease in hospital admissions, a 13% decrease of acute care visits, but no decrease in ED visits for asthma (AHRQ 2007).

Therefore, by averaging the results of these studies, it is anticipated that successful implementation of the CPG at WRAMC would result in a decrease in hospitalizations of 50%, a decrease in acute care visits of 33%, and a 25% decrease in ED visits.

The following table demonstrates anticipated cost savings for WRAMC based on successful CPG implementation. HEDIS MTF data for pediatric hospitalizations, acute

care and/or ED visits for WRAMC in 2008 was retrieved and anticipated rates post-CPG implementation based on the above projections were determined.

*Table 1: Anticipated cost savings*

	2008	Cost	Post EBP	Revised Cost	Savings
Hospitalization	28	\$163,828	14	\$81,914	\$81,914
Acute Care visit	1028	\$90,464	690	\$60,720	\$29,744
ED visit	144	\$45,072	108	\$33,804	\$11,268
TOTAL		\$299,364		\$176,438	\$122,926

## **Conclusion**

While the military healthcare system does not routinely focus on cost-benefit or cost-effectiveness analyses, in light of the current economic climate and discussions of healthcare reform, these areas need to be assessed. Only interventions that are proven to be effective and efficient in providing quality health care should be promoted. Successful implementation of the asthma CPG at WRAMC can and should be used as an example for other MTFs. Conservatively, this MTF would experience a savings of \$122,926.00 per year after implementation of the asthma CPG. This will ultimately improve asthma care not just for patients at WRAMC, but for military family members throughout the Department of Defense. Successful implementation of an asthma CPG in the MTF would show significant cost savings for the MTF and taxpayers.

The specific approach used at WRAMC will depend on the organizational assessment of the pediatric clinic. As noted in the literature, a multifactorial, interactive approach is more likely to be successful than a traditional passive implementation of the CPG (O’Laughlen, et al, 2009).

## CHAPTER THREE: PROJECT METHODS

### **Research Model**

The change process is best facilitated by the use of a formal structured model that has been proven to be successful with EBP implementation. The Stetler Model of Research Utilization and Evidence-Based Practice was chosen as the tool to facilitate this project. Yoder-Wise (2007) noted that this model provides direction for both individuals as well as groups, and is ideal for use by a nurse leader. The Stetler Model is a linear model that has been previously utilized with EBP implementations. Although linear, the Model is composed of five steps that allow for frequent evaluation and revisions of the initial issue.

**Preparation.** The problem (lack of compliance with CPG) was initially identified over two years ago via anecdotal reports from pulmonary colleagues, medical record review or patient interview showing inappropriate medication prescription, lack of follow-up, etc. The preparatory step began over one year ago with a formal literature review regarding CPG usage and implementation as well as an organizational assessment of the participating pediatric clinic.

**Validation.** A literature review related to various aspects of asthma CPG implementation was completed. Evidence shows that compliance with all or parts of the CPG can enhance patient outcomes.

**Comparative Evaluation/Decision Making.** The areas to be evaluated as noted by Burns and Grove (2005): fit of the evidence within the pediatric clinic, feasibility of using the research findings, and substantiating the evidence will be discussed further under “organizational context”.

**Translation/Application.** CPG implementation is a highly variable process and review of the literature identified several methods to facilitate the change process. No one technique was identified as superior regarding CPG implementation. As noted in Melnyk and Fineout-Overholt (2005), “passive education is rarely effective....Consider multiple strategies, e.g., interactive education, opinion leaders, educational outreach, audit, etc” (p 191).

The majority of successful implementation strategies combine provider education with some form of medical record revision and/or provider prompting tools (Doherty, et al, 2007; Halterman, et al, 2006; Lesho, 2005; Stone, Schweikhart, Mantese & Sonnad, 2005; Wood & Hill, 2009)

As noted in the “Organizational Context”, the stakeholders (pediatric providers) are a cohesive group that readily accepts education and process and improvement. Demonstrating the “value added” (improved outcomes) of CPG implementation should ensure support from the participants. The pediatric pulmonary service has already embraced the use of the asthma CPGs and their support will be instrumental in this change project.

After review of the literature and organizational assessment, a combined approach utilizing provider education and extrinsic tools will be utilized.

- a. Provider education will be both formal (morning lectures) as well as informal (journal club, verbal reminders regarding CPG). Education will involve not just the updated CPG but also orientation to the reminder tools. Table 1 shows the key components that will be included in Provider education.

- b. The electronic medical record (EMR) will be modified to include an asthma action plan (Appendix D) and asthma control test (Appendix E) which have reminders of levels of severity and treatment recommendations
- c. Visual aids of posters and reminders of asthma care in provider's offices and waiting rooms.
- d. Patient education sheets given to patients presenting with a history of asthma.

The posters and other handouts are available free of charge from the Office of Quality Management, Army Medical Command.

**Evaluation.** While the Stetler Model allows for both informal and/or formal evaluation, this project will concentrate on a formal method of process improvement to ensure the acceptance and continued compliance with CPGs. This project will be identified as a formal Process Improvement initiative and outcomes will be monitored and presented quarterly during the Department PI meeting. HEDIS data will continue to be monitored monthly and variance from CPG practice will be addressed with individual providers by this author. The use of automatic prompts in the EMR will facilitate the CPG becoming standard practice in the pediatric clinic.

### **Organizational Context**

The evidence-based project will be implemented at the Walter Reed Army Medical Center (WRAMC) pediatric clinic located in Washington D.C. The pediatric staff consists of over 150 military and civilian employees; this includes more than 80 physicians, nurse



practitioners and physician assistants. Patients are empanelled to a primary care provider (PCP) and the goal is that the majority of appointments (well or acute) are with that PCP.

WRAMC supports Graduate Medical Education and is a training site for medical and nursing students, pediatric residents, as well as five pediatric subspecialty fellowship programs (neonatal, endocrinology, infectious hematology-oncology, and gastroenterology). It also conducts pediatric training for both nursing and enlisted medical specialties.

There are numerous factors that may both contribute to or detract from the successful implementation of the revised DoD/VA CPG. An analysis of the pediatric clinic strengths, weakness, opportunities and threats (SWOT) was completed.

**Strengths.** The pediatric clinic enjoys numerous “strengths” in both personnel and environment. There is a high degree of commitment to GME, quality patient care, patient safety and Process Improvement (PI). Daily morning report lectures and monthly PI meetings are all well attended by a communicative, collaborative, multi-disciplinary group. The clinic is well staffed with both providers (residents and staff) and nursing personnel (RNs, LPNs, assistants). There is high staff satisfaction as evidenced by the high retention rates. The pulmonology clinic employs a full-time pediatric respiratory therapist who is available to perform pulmonary function tests on all patients – not just those scheduled with the pulmonology clinic, as well as a certified asthma educator. The Armed Forces Health Longitudinal Technology Application (AHLTA), is the current outpatient EMR and is accessible throughout the hospital as well as the region. Providers have access to full medical records, including radiology and lab results. Providers have also been issued

laptop computers and can, when appropriately configured with security measures, access the EMR system from home.

**Weaknesses.** Unfortunately, there are some weaknesses in the pediatric clinic. While the civilian staff is stable, the military members of the staff are subject to frequent deployments. There was no formal implementation process for previous CPGs. The EMR, while an advantage, is also a weakness. AHLTA is separate from the inpatient EMR, Essentris. Furthermore, patients may email a Provider on Outlook, which is not a secure system. The computer system is frequently slow and will often “freeze” or stop working for brief periods of time. Another weakness that needs to be addressed is the data base that is used to identify pediatric patients with asthma. The Healthcare Effectiveness Data and Information Set (HEDIS) is used by WRAMC, as well as its higher headquarters (Medical Command), to track certain quality indicators (inhaled corticosteroid use, emergency department visits, hospitalizations, etc) for children 5-21 years of age who were diagnosed with asthma. The major weakness is that the data base is often incorrect and has identified children who were inappropriately diagnosed. The list is reconciled monthly by comparing patients who appear on the list with a careful review of their EMR to confirm diagnosis, acute care visits and medications ordered. It is time-consuming, but necessary, to correct the list prior to analyzing the data.

**Opportunities and Threats.** Modification of the EMR is time-consuming, but possible. The addition of an asthma action plan will be part of the CPG implementation plan. WRAMC is currently integrating with the National Naval Medical Center (NNMC) and within the integration process, both opportunities and threats arise. The opportunity for standardization of clinical practice and monitoring of patient outcomes for a larger

patient population is encouraging. The current Chief, Pediatrics (Army) was selected to be the Chief of the integrated pediatric department, therefore, continuation of the asthma CPG at NNMC should be feasible in the future. One significant advantage that the military health care system offers in contrast to civilian health care system is that cost or access to care is rarely a barrier to receiving adequate medical care. TRICARE insurance mandates strict adherence to appointment access timelines and prescriptions filled at a military treatment facility are free.

In accordance with Step 3 of the Stetler Model, the overall assessment of the pediatric clinic shows a clinic that has high morale and a high commitment to GME, process improvement and quality patient care, therefore implementation of an evidence-based protocol should be accepted. The weakness of the organization, specifically, electronic medical record issues and frequent turnover of military providers will need to be addressed so the implementation process can be solidified into the culture of pediatric care at WRAMC.

### **Outcomes to be Measured**

As noted in the literature, several objective clinical outcomes have been measured as an indicator of CPG compliance and improved patient care. Those indicators that will be measured after CPG implementation at WRAMC are:

1. Emergency Department visits
2. Acute Care visits
3. Hospitalization

Compliance with the asthma CPG will improve outcomes in those three specific areas. Key interventions that will also be tracked include the use of a written asthma action plan and prescription of inhaled corticosteroid for any severity of persistent asthma. These interventions have been highlighted in several articles as well as the current asthma CPG (Sullivan, et al, 2008; Zemek, et al, 2008; NHLBI, 2007).

### **Method for Data Collection and Analysis**

The proposed project is a pre- and post-evaluation design. Pediatric patients with asthma will be identified via the Healthcare Effectiveness Data and Information Set (HEDIS). A retrospective chart review utilizing HEDIS will be completed prior to project implementation. The review will encompass the three month time period immediately prior to CPG implementation. HEDIS provides current rates of hospitalization, emergency department care and acute care visits. Review of the electronic medical record (EMR) will verify accuracy of the HEDIS data.

A second retrospective review of the EMR and HEDIS patient list will be undertaken three months after CPG implementation. The same outcomes will be measured and data analyzed. Both samples will be relatively small size (fewer than 150 patients) and equal variance will be tested and verified. Therefore, the paired t-test will be used for statistical analysis.

### **Human Subjects Considerations**

No individual patient identifiers will be maintained. This study was determined “exempt” and letters of exemption were received from the Institutional Review Boards (IRB) at both The Catholic University of America and WRAMC.

**Sustainability**

Use of the CPG will be maintained via ongoing monitoring and evaluation of HEDIS patient list as well as medical record review by this author. This project will be established as a formal process improvement project and data will continue to be collected at 3 month intervals. Analysis of results will be discussed quarterly in Pediatric Department Process Improvement meetings. However, for purposes of this academic program, data will be collected initially, and then 3 months post-CPG implementation to identify short-term compliance and direct revisions to implementation.

**Relevance to Nursing**

Numerous studies show the value of nurses, both Nurse Practitioners and staff nurses, being directly involved in asthma care (Guevara, et al, 2003; Borgmeyer, et al, 2008; Newcomb, 2006). Wiener-Ogilvie, et al (2008) explored how teamwork and interprofessional relationships impacted asthma care. Groups that were highly compliant with asthma care had more positive communication and specifically identified nurses as an integral part of the asthma care team (Wiener-Ogilvie, et al, 2008).

Education is a key component of the asthma CPG. One of the basic functions of the nurse is patient education. Nurses can and should be utilized in all areas of patient education and asthma management. Formal group classes, individual patient (parent) education, medication technique and adherence, symptom control, use of the asthma action plan are all examples of asthma topics that nurses can be responsible for. Several studies showed the value of utilizing nurses in the management of asthmatic patients (Wiener-Ogilvie, et al, 2008; Grol & Grimshaw, 2005). .

Nurses have a tremendous role in optimizing asthma care for children and families and enhancing their quality of life. Numerous studies document that the quality of care and patient satisfaction ratings of Nurse Practitioners is equivalent or higher than their primary care physician counterparts (Benkhert, Peters, Tate & Dinardo, 2008; Brown, 2007; Carter & Chochinov, 2007). One study also showed comparable care given by PNPs to hospitalized pediatric asthma patients (Borgmeyer, et al, 2008). These studies are important, not just for nurses, but also the patients they care for. The DNP is the ideal person to combine clinical expertise with the advanced knowledge of research utilization and systems theory to be the change agent for this project.

Table 2: Provider education

Key points of DoD/VA CPG:	Components of patient education:
Severity classification	Asthma knowledge
Assessment of control	Written asthma action plan
Use of ICS for persistent asthma	Home management, to include worsening symptoms
Spirometry on all patients >5yo	Trigger identification and avoidance
Management of comorbid conditions	Control of comorbid conditions
Emphasis on Asthma action plan	
Decreased emphasis on peak flow	

## CHAPTER FOUR: PROJECT IMPLEMENTATION

### **Introduction**

Implementation of a clinical practice guideline is a highly variable process. As noted in Chapter Two: Synthesis and Analysis of Supporting Literature, no one technique was identified as superior regarding CPG implementation. The goal of this project was to implement the Department of Defense/Veteran's Administration (DoD/VA) asthma clinical practice guideline (CPG) in the pediatric clinic of a major military medical center. Therefore, the use of a formal structured model was needed to facilitate the change process and monitor progress. The Stetler Model of Research Utilization and Evidence-Based Practice was chosen as the tool to facilitate this project, as noted in Chapter Three: Project Methods.

Two key components of the CPG were identified as essential to providing quality care to pediatric patients with asthma: the use of inhaled corticosteroids (ICS) for any level of persistent asthma and the use of a written asthma action plan provided to patient/parents. A third component, use of spirometry for patients older than 5 years of age, was also tracked by this author. Although not identified in the literature as specifically impacting asthma outcomes, this metric is tracked by other military services and communication with Medical Command indicates the Army will soon begin the same practice (H. Wojtczak, personal communication, 5 August 2010). The DoD/VA asthma CPG recommends annual spirometry for all patients diagnosed with asthma who are the age of five years old.

It is anticipated that adherence to those interventions (specifically, use of ICS and written asthma action plan), would improve patient outcomes in three specific areas:

decreased visits to the Emergency Department, decreased acute care visits and/or decreased hospitalization rates.

### **Process Application**

Step four of the Stetler Model, “Translation/Application”, is the part most closely aligned with actual implementation of the evidence-based project. Translation/application, or implementation, began with a review of the literature to discover possible ‘best practices’ for CPG implementation. Unfortunately, no one technique was identified as being superior to successful CPG implementation. The majority of research suggested combining provider education with some form of medical record revision and/or provider prompting tools (Doherty, et al, 2007; Franciso, B.D. & Rood, T.L, 2010; Lesho, 2005; Stone, Schweikhart, Mantese & Sonnad, 2005; Wood & Hill, 2009).

After literature review, an organizational assessment was completed. The assessment confirmed that the pediatric providers are a cohesive group that readily accepts education and process improvement. The numerous strengths of the pediatric department (transformational leader, commitment to graduate medical education and quality patient care and safety, access to electronic medical record (EMR), etc) as noted more fully in Chapter 3, aided significantly in the facilitation of this project. If the barriers to implementation could be overcome, then successful implementation was anticipated.

Two major barriers to implementation were identified. First, the EMR, while accessible, is often slow and modifications are difficult to accomplish. , The second barrier identified was the actual data base available. The Healthcare Effectiveness Data and Information Set (HEDIS) is used by WRAMC, as well as it’s higher headquarters (Medical Command), to track certain quality indicators (inhaled corticosteroid use, emergency



department visits, hospitalizations, etc) for children 5-21 years of age who were diagnosed with asthma. The major weakness is that the data base is often incorrect and has identified children who were inappropriately diagnosed. The list is reconciled monthly by comparing patients who appear on the list with a careful review of their EMR to confirm diagnosis, acute care visits and medications ordered. Both of these barriers need to be addressed to aid in successful implementation of key components of the CPG and will be addressed further.

A combined approach utilizing provider education and extrinsic tools was utilized by this author, after review of the literature and organizational assessment. Immediately prior to project implementation, a retrospective chart review was completed via the HEDIS data base. This chart review covered patients enrolled in HEDIS during the 3-month period of March, April and May 2010. A total of 338 patients were originally identified on the HEDIS data base. After review of the EMR, 11 patients were removed due to inappropriate diagnosis (eg: prescribed ICS for eosinophilic esophagitis, albuterol given for isolated episode of wheezing with no recurrence of signs/symptoms suggestive of asthma, cystic fibrosis, etc). The remaining 327 electronic medical records were reviewed to verify appropriate diagnosis and to identify the presence of acute care visits, a prescription for ICS, asthma action plan and/or recent (within twelve months) spirometry. Emergency Department visits and/or hospitalization information are not consistently documented in AHLTA, therefore, the HEDIS data base continued to be the sole source of that information. This baseline data is presented in Table 1. A second retrospective chart review will be completed 3 months post CPG implementation. Full evaluation of outcomes will be presented in Chapter 5.

Table 3: *Baseline data*

	March	April	May	Total	Percent
Total	101	124	102	327	
0-4 years	22	21	22	65	20%
5-21 years	79	103	80	262	80%
ED Visits	27	23	27	77	24%
Acute Care visits	84	87	82	253	77%
Hospitalization	7	2	3	12	4%
Asthma Action					
Plan	17	12	18	47	14%
ICS	71	89	86	246	75%
Spirometry	27	26	35	88	34%

**Provider Education.** A variety of methods were utilized to educate the majority of pediatric providers regarding implementing the chosen two key components of the DoD/VA asthma CPG. The key components (use of ICS and asthma action plan) were considered essential to improve patient care. The importance of spirometry in children was discussed, but emphasis was given to those interventions that were identified in the literature as most significant to improvement in asthma outcomes. No education session attempted to review the entire CPG i.e. use of algorithms, inpatient management, etc.

This author partnered with a staff general pediatrician to provide four lunch-time “mini-inservices” to both pediatric residents and staff physicians in June and July 2010. This

time period ensured the majority of both new interns and senior residents and/or staff physicians received the education. As an incentive, refreshments were provided to the participants. Attendees were provided with a laminated copy of the Step-Care for Medications required to maintain long-term control (appendix C), a copy of an asthma action plan (appendix D) and my business card containing all contact information should they require any further education or assistance. An attendance record was kept by this author. Table 2 shows the key components that were included in the provider education sessions. One hundred percent (4/4) of the general staff pediatricians attended one or more of the sessions and sixty-nine percent (23/33) of the pediatric residents attended. In all, a total of seventy-three percent (27/37) of the general pediatric providers received direct education by this author. The response was overwhelmingly positive and the attendees verbalized a desire for more instruction in basic asthma care (use of different medication devices or spacers).

The education continued in August 2010 with four additional education sessions provided during morning report. “Morning report” is a mandatory meeting from 0730-0900 every workday. This meeting involves discussion regarding current inpatients as well as “case of the day”, Grand Rounds, or other educational offerings. All general and specialty staff, residents, medical students attend this meeting. A third year pediatric resident who attended one of the earlier lunch-time education sessions and elected to champion a Process Improvement project based on the use of the asthma action plan, presented information regarding the CPG (specifically use of asthma action plan and ICS) at morning report. An attendance record, kept by the Graduate Medical Education

Director, verified the attendance of the remaining 10 residents who were not able to attend the education sessions presented in June or July.

**Extrinsic Tools.** The use of external tools or provider prompts were utilized by this author to remind staff about pertinent issues discussed during the education sessions. Electronic mailing (“email”) reminders of the CPG were sent to the general pediatric group in July and August after education sessions. In addition, laminated posters regarding asthma action plans were placed in patient waiting areas and exam rooms (Appendix F). These posters were to serve as visual reminders for staff regarding use of the CPG and for patients to address the issue with their Provider.

To assist the general pediatric staff in providing consistent, appropriate asthma education to patients, a fourteen-page education booklet was written by this author. This booklet encompasses general asthma education to include basic pathophysiology, use of control versus rescue medication, introduction to the asthma action plan, emergency follow-up, etc. All patients either newly diagnosed, or those requiring education ‘refreshers’ are given a copy of “Asthma: Facts to Help Me Live and Breathe”. The front and back covers are shown in Appendix G.

Another patient education tool handout was also made available to the general pediatric providers (Appendix H). An information sheet giving detailed instruction on the use of the valved holding chamber (“spacer”) with the metered-dose inhaler was written by this author and a pediatric respiratory therapist assigned to the pediatric pulmonology service. This handout is available in the general pediatric clinic exam rooms as well as the treatment room and is given to all patients who are prescribed an ICS or rescue medication to be given by metered-dose inhaler.

**Electronic medical record.** Unfortunately, modification of the EMR locally was not possible. After extensive discussion with the Informatics Department at WRAMC, a trial of an electronic asthma action plan was attempted by this author. Despite numerous modifications, an effective and efficient electronic asthma action plan was not feasible. The use of the WRAMC electronic asthma action plan was too time-consuming in that it took between thirty and forty five minutes to complete one form. Therefore, as accepted by the Stetler Model, a modification of the original implementation plan was made and the use of a locally-created electronic asthma action plan was abandoned. The creation of a DoD/VA electronic asthma action plan was also attempted. That attempt was also unsuccessful but a partnership with the DoD/VA continues. In place of an electronic asthma action plan, this author coordinated with WRAMC publications to mass produce color printed asthma action plans that were placed in all exam rooms. The nursing staff is responsible for assessing and restocking exam rooms as needed.

**CPG Partnerships.** It is essential to have leadership support when implementing any change process. However, as important as leadership is, the support of the practitioners who will be involved in the daily utilization of the CPG is paramount to a successful program. The use of clinical “champions” to facilitate local implementation of DoD CPGs is essential (Nicholas, Farley, Vaiana & Cretin, 2001). This project was fortunate to have both clinical support as well as support from the most senior leadership at Medical Command.

Local support was achieved via a group of resident physicians who championed a process improvement project regarding CPG implementation. As noted above, a third year Resident has championed a group of four residents who are involved with the CPG

implementation, specifically the use of written asthma action plans provided to patients/families. This group was formed as part of the Residency program requirement and, as its members are from all three year groups, will continue through 2012. This group is supported by a staff general pediatrician and this author is a clinical advisor. After much discussion, it was decided that the team would focus on the use of the asthma action plan. This team has been highly motivated to encourage their peers to increase the awareness of asthma in the pediatric population, adherence to the asthma CPG, and utilization of the asthma action plan. The team continues to work closely with this author to ensure increased application of the CPG. This project is ongoing as the team includes Residents at all stages of their training.

The Department of Defense (DoD) and Veteran's Administration (VA) worked together to research and publish the most recent asthma CPG in January 2010. In January 2011, the DoD/VA compiled a working group to create patient and provider resources that will allow the clinical user to practically implement the CPG at the user level. This author was selected to continue to work with the DoD/VA to create a "tool kit" of material for the pediatric population (to include, providers, patients and parents). It is anticipated that the tool kit will have not only paper resources – but many electronic resources. The group communicated via electronic mail, webcasts, and weekly teleconferences. The group consisted of many of the same individuals that were involved with the revision of the CPG, including providers, nurses, clinical pharmacists, respiratory therapists and administrative personnel. Patients and/or family members were not included in the original working group but will be utilized as reviewers prior to publication of any material. The working group met in San Antonio, Texas, in April 2011 to review progress toward the goal of

successful dissemination and implementation of the CPG. The use of an effective and efficient electronic asthma action plan was identified by many of the working group as a major goal of successful CPG implementation. However, even with the support of the DoD and VA, information technology specialists assigned to the group, were unable to successfully create a user-friendly, efficient and effective electronic asthma action plan. Therefore, a written asthma action plan was created and, after review, will be included in the tool kit. This partnership, like the Residency partnership, is ongoing but will benefit not just WRAMC, but all DoD medical treatment facilities.

## **Conclusion**

The Army Medical Command (AMEDD) was aware of wide-spread user concerns regarding the HEDIS data base. Access to the data base was not available for several months as the AMEDD changed servers and worked on correcting deficiencies. The updated server now allows local users (after proper security clearance and training) to more easily reconcile the HEDIS action list. This will allow the user to better identify and track patients with asthma who require closer follow-up or intervention. This should significantly improve the overall usefulness of the data base.

Successful evidence-based practice implementation involves evaluation. After implementation of the CPG, a second three-month retrospective chart review was completed in December 2010, January and February 2011. The evaluation will focus not only on actual outcomes, but also include a discussion of additional areas of concern (limitations of study, barriers, etc) as well as areas for future study. As noted previously, this evidence-based practice project is an ongoing process. This project is part of a formal

Process Improvement initiative and outcomes will be monitored quarterly and presented during pediatric department PI meetings.



## CHAPTER FIVE: RESULTS, EVALUATION, IMPLICATIONS, CONCLUSION

### **Introduction**

Sustainment of Clinical Practice Guideline (CPG) implementation is generally recognized as the most difficult phase in the change process (Doherty, et al, 2007; Joint Commission, 2001; Mangione-Smith, et al, 2005, Nicholas, et al, 2001). The Stetler Model encourages a continuous evaluation process of both formal (audits, quality assures, outcomes management) or informal (patient or staff input) activities. This continuous process should be used to either continue the Evidence-Based Practice (EBP), with or without modification, or reject (stop) the practice (Burns, 2005; Stetler, 2001). This information should then be relayed back to the interested parties as a means to continue (or sustain) the practice. This author focused on formal evaluation processes as measurement of CPG implementation success.

### **Results**

A 3-month retrospective chart review was performed before (March-May 2010) and after (December 2010-February 2011) the asthma CPG was implemented. The two groups had similar ages, sex, and sponsor status (Table 1).

**Table 4:** *Comparison of groups pre/post intervention*

	Pre	Post
Total	327	289
0-4 years	65	65
5-21 years	262	224
Male	184	163
Female	143	126
Active Duty Family Member		
Member	198	183
Retired Family Member	129	106

Initially, 338 electronic medical records were reviewed from the HEDIS data base March through May 2010. Patients are automatically placed on the HEDIS list based on diagnosis of “asthma” (or ICD-9 code equivalent) during hospitalization, ED or acute care visits and/or prescriptions filled for an asthma control medication (ICS as well as medications such as leukotriene receptor antagonist or theophylline). Subsequently, 11 records (3%) were excluded due to incorrect appearance on the data base. These patients may have been prescribed an inhaled corticosteroid (ICS) for another diagnosis (eg: cystic fibrosis or eosinophilic esophagitis) or been inaccurately labeled with “asthma” (eg: one time ED visit for infant with wheezing during upper respiratory infection).

The HEDIS data base provided demographic information (age, sex, beneficiary category), Primary Care Manager, hospitalization, ED visit, acute care visit, name of long-

term controller medication (if prescribed) and most recent date dispensed, and spirometry testing date.

The remaining 327 electronic medical records (EMR) were individually reviewed to verify the above information as well as determine prescription of inhaled corticosteroid as daily controller medication and presence of an asthma action plan, which is not tracked via HEDIS. The asthma action plan is not documented consistently in the EMR. It may be either written in as an "add note", scanned electronically, annotated via "additional therapy: asthma action plan", or documented in the "plan" section of the EMR. Any annotation in the EMR that an asthma action plan was "discussed", "provided", or "reviewed with parents" was considered acceptable proof of presence of a written asthma action plan.

Results of EMR review prior to the CPG implementation are shown in Table 2.

**Table 5:** *Pre-implementation data*

	Pre-March	Pre-April	Pre-May	Total	Percentage
total	104	129	105	338	
inappropriate	3	5	3	11	
N	101	124	102	327	
ED	27	23	27	77	23%
Acute care	84	87	82	253	77%
Hospitalization	7	2	3	12	3%
Action Plan	17	12	18	47	14%
ICS	71	89	86	246	75%

After education and training was provided to the staff (June through August 2010), a second 3-month retrospective chart review was completed from the HEDIS data base November 2010 through January 2011. A total of 305 patients were identified on the HEDIS data base, however, similar to the pre-implementation group, 16 were identified as inappropriate diagnosis and removed from further analysis. Post-CPG implementation data is shown in Table 3.

**Table 6:** *Post-implementation data*

	Post-Dec	Post-Jan	Post-Feb	Total	Percentage
Total	94	98	113	305	
Inappropriate	3	4	9	16	
N	91	94	104	289	
ED	13	17	20	50	17%
Acute Care	70	74	84	228	79%
Hospitalization	7	10	8	25	9%
Action Plan	31	43	54	128	44%
ICS	70	73	71	214	77%

Following implementation of the CPG, there was a 6% decrease in the percentage of ED visits as noted in HEDIS. However, there was a slight increase in rates of acute care visits and hospitalizations (2% and 6%, respectively). A small (2%) increase was also noted in the use of ICS. There was a larger increase in use of written asthma action plan post-CPG implementation (14 to 44%).

Healthy People 2020 identifies asthma as a health improvement priority topic. Baseline data as well as target goals have been identified for several of the objectives measured in this project (emergency department visits, inpatient hospitalization and use of asthma action ("management") plan. Healthy People 2020 does not identify a goal for acute care visits. Nor does Healthy People 2020 identify a target goal for use of ICS, however, HEDIS has identified a goal of 95.1% for "appropriate medication for asthma".

The military treatment facility had 3200 beneficiaries enrolled in the general pediatric clinic during the study period. Therefore, the MTF did NOT meet the HP2020 target goals for emergency department visits (goal: 95.5/10,000 population; MTF: 50/3,200) or hospitalization (goal: 18.1/10,000; MTF: 25/3,200). The MTF did surpass Healthy People 2020 goals for use of a written asthma action plan (goal: 36.8%; MTF: 44%). While the MTF use of ICS (77%) is significantly lower than HEDIS goal (95.1%), it should be noted that HEDIS measures "appropriate medication for asthma" as ICS, leukotriene agonist, cromolyn sodium, theophylline and other medications that are not recommended as first-line treatment for asthma. When the HEDIS medication criteria is used, the MTF surpasses the HEDIS goal.

## **Evaluation**

The goal of this project was implementation of the DoD/VA asthma CPG in a Military Treatment Facility pediatric clinic. The research hypothesis was that after implementation, outcomes would improve in three specific areas: Emergency Department visits, Acute Care visits, and rates of hospitalization. As these are long-term measurements, additional, short-term goals were also tracked for improvement: the use of a written asthma action

plan (AAP) and prescription of inhaled corticosteroid (ICS) for any severity of persistent asthma.

The independent variable was the use of the CPG. The dependent variables were the five long and short term outcomes. These variables were tested with the following formula where:  $H(0)$  equals the null hypothesis. That is, the probability of Emergency Department visits in the experimental group is the same as the probability of ED visits in the control group. This formula was repeated for each five long and short-term variables.

E = experimental group, those in the post-CPG implementation group

C = control, or pre-CPG implementation, group

P = probability

$H(0)$  [null hypothesis] =  $p(\text{variable E}) = p(\text{variable C})$

$H(r)$  [research hypothesis] =  $p(\text{variable E}) \neq p(\text{variable C})$

A Z-test for proportions was performed to determine if the proportions from two independent groups (pre-CPG implementation and post-CPG implementation) were significantly different from one another. All statistical analysis was done using Joosse's In-silico z-test calculator (Joossee, 2011).

**Table 7:** *Statistical results*

	Control (pre- CPG) %	Experimental (post-CPG) %	Z-test	p-value (95% CI)
ED visits	23.5%	17%	1.8515	.0641
Acute care visit	77%	79%	.597	.5502
Hospitalization	4%	9%	2.54	.0114
Written AAP	14%	44%	8.269	<.0001
ICS	75%	74%	.2843	.7762

Using z-test for proportions with 95% confidence interval, the null hypothesis was not supported with regards to acute care visits, ED visit, rate of hospitalization, or use of ICS. That is, implementation of asthma CPG did not result in significant improvements in those areas. While there was a decrease in the rate of ED visits, it was not statistically significant. There was a small, but statistically significant increase in the rates of hospitalization post-CPG implementation. The null hypothesis was supported with the use of written asthma action plans. That is, there was a significant increase in the use of written asthma action plans post-CPG implementation.

The increase in hospitalization, post asthma action plan implementation, has been documented in the literature. Several studies related to written asthma action plans demonstrated a propensity towards decreases in acute care and ED visits - but not hospitalizations (Bhogal, Zemek & Ducharme, 2006; Cloutier, 2006; Coffman, 2008). In a systematic review of 13 studies related to asthma action plans, five showed an increase in

hospitalization rates when asthma action plans were utilized (Kessler, 2011). The precise reason for this has not been determined.

## **Implications**

Several concerns were identified over the course of this project implementation. These may be separated into two categories: barriers and facilitators. Identification and evaluation of these issues may assist during future implementation projects.

### **Barriers.**

1. The HEDIS data base was inaccessible for a five-month period (December 2010 to March 2011) as it underwent system updates and security patches. Unfortunately this coincided with post-implementation data collection. When the data base resumed, all information was easily retrievable. In addition, the upgrades allow users to more easily track and make corrections to their data bases.
2. The electronic medical record allowed access to all patient information, however, there was no consistent documentation of asthma action plan i.e. the plan may have been scanned in, written in either the “Subjective/Objective” or the “Assessment/Plan” portion of the note, or simply annotated by a ‘drop-down’ menu noting “patient education: asthma action plan”. Therefore, review of the EMR was time consuming and may not be practical for continuous 100% monitoring of compliance.
3. A goal of this project was modification of the EMR to include an electronic asthma action plan. Unfortunately, even with the support of the Department of



Defense/Medical Command, a revision of the EMR has been impossible thus far. This work is ongoing.

4. This project was limited by a 3-month post-CPG implementation data collection. This brief time period may not have been adequate to identify a significant change in acute care and/or hospitalizations, which may have more seasonal variation.
5. Asthma has seasonal peaks. Pre-implementation data was collected in the spring (historically, a 'low' asthma period) with post-implementation data collected in the winter. Upper Respiratory Infections (URI's) are the main trigger for asthma flares in children. Therefore, the increase in acute care visits and hospitalizations may have been partially caused by an increase in URI and/or viral illness during the winter months. Ongoing data collection will determine if the increase in acute care visits and hospitalizations is the result of seasonal variation versus CPG implementation.
6. As noted previously, the hospitalization rate for asthmatics admitted to the MTF already exceeded the HP2010 goal pre-CPG implementation. The reasons for this may be multi-factorial and have not been formally studied. However, personal observation notes that, physician preference may be one factor. Some less experienced resident physicians are more inclined to admit patients after only a brief treatment and observation period in the ED or clinic. Other providers, perform more extensive treatment and when all outpatient options have been exhausted, resort to hospitalization. Similarly, the ward is staffed by a rotating cadre of experienced attending pediatricians, however, their

specialties vary. For example, when the pediatric pulmonologist is ward attending, may get a more extensive treatment plan in the clinic or ED with appropriate clinic follow-up versus admission.

7. Nursing staff was not included in the formal teaching. Nursing personnel have taken the responsibility to stock paper asthma action plans in the exam rooms, however, they were not included in the formal teaching. Inclusion of all staff may have increased participation and enthusiasm for the project.

### **Facilitators.**

1. As noted above, nursing staff was not included in the formal teaching sessions, however, some staff did attend. Regardless of attendance, nursing staff was approachable and voluntarily took the initiative to monitor paper asthma action plans and restock provider exam rooms as needed. This team work is indicative of the general pediatric staff.
2. Medical staff was involved in educational sessions and approached this author requesting additional education regarding pediatric asthma care. The significant increase in the use of written asthma action plans demonstrates the increased education that patients/parents received. This increased education may actually have facilitated an increase in the use of acute care visits as patients/parents felt more aware of their child's asthma symptoms and sought care earlier. This is evident as several parents have commented to this author that, with an asthma action plan, they "finally knew what to do" with regards to monitoring their child and seeking emergency care.

3. All patients involved were empanelled to the general pediatric clinic and had full medical insurance (TRICARE Prime). The rapid availability of provider or Emergency Department access at no cost, free medications (when filled in the MTF pharmacy), free (or reduced cost) hospitalization, may have falsely increased the numbers in those areas. Patients may be more likely to utilize those resources due to the low (or no) cost.
4. The EMR, while burdened with some limitations, was readily available, and did provide access to documentation. There was no need for additional surveys or provider recall which may have skewed the data.
5. The project implementation began during the summer 2009. Thus, the maximum number of new residents and staff were available for asthma CPG education.

## **Conclusion**

Asthma continues to be one of the most common chronic pediatric illnesses, with a current prevalence rate of 9.4% for children less than 18 years of age (CDC, 2011).

Asthma affects not just the child, but also his/her family, school systems, medical facilities, communities and our nation. The cost of asthma includes not just direct, monetary, costs, but also indirect costs associated with loss of school time for the child, lost productivity for the parents, and decreased quality of life related to activity or sleep disturbances.

Numerous studies indicate that use of CPGs improves the overall quality and value of health care services (HP2010; JCR, 2004). Although this project did not produce significant improvement in most of the areas identified, there was significant improvement

in the utilization of written asthma action plans. Although asthma action plans have been associated with increased hospitalization rates, they have also shown to improve quality of life indicators such as school or work absences, decreased daytime symptoms, activity limitations and nighttime awakenings (Cooper, 2010; Kessler, 2011).

Although there was not significant improvement in the majority of outcomes measured, the primary goal of this project was implementation of the asthma CPG. No one method of CPG implementation has been proven to be more successful than another method according to the literature. This author used a variety of techniques to include small group education, larger group tutorials (morning report), electronic and hard copy reminders (posters, written asthma action plans). Through the process of this evidence-based practice project, the primary goal was achieved in that awareness of the DoD/VA CPG was drastically improved. Numerous Providers have voiced approval of the DoD/VA CPG and an increased understanding of its usefulness. Although not formally measured, this provides a basis for future in depth study and analysis.

This project will be sustained via ongoing monitoring and evaluation by this author. It has been identified by the pediatric command group as a Process Improvement initiative and will be reported to the Command quarterly. Therefore, monitoring for the problem of seasonal variation which may have impacted the data will be accomplished.

In September 2011, the Medical Treatment Facility (MTF) involved in this project was integrated with the local Navy MTF. The majority of patients transitioned to the new facility, however, some elected to enroll at the MTF in Virginia or to obtain civilian healthcare. HEDIS will continue to be used as the repository for pediatric patients identified with asthma. An important development for this project is that the new

integrated MTF Command has expressed approval for this project. Asthma “clinical champions” have been identified and MTF Command will be receiving quarterly reports regarding pediatric and adult asthma management.

Future research will focus on direct cost-effectiveness (improvements in Emergency Department and/or hospitalization rates) as well as improved quality of life indicators (eg: improved asthma control test scores or documentation of decreased missed school/work). This project should be used as an example for other MTFs to ensure military beneficiaries received the most current, evidence-based care available.

Wiener-Ogilvie and Huby (2008) demonstrated that health care organizations with increased communication, trust and teamwork were more successful in sustaining clinical changes. This integrated MTF has shown itself to be a proactive, progressive organization. Therefore, this author is confident this evidence-based project will continue contribute towards quality healthcare for children with asthma.

APPENDIX A  
ASSESSMENT OF SEVERITY

SEVERITY		Intermittent	Mild Persistent	Moderate Persistent	Severe Persistent
Impairment	Symptoms	<2 days/wk	>2days/week but not daily	Daily	Throughout day
	Night awakenings	<2x/month	>2x/month	>1x/week but not nightly	Nightly
	Use of “rescue” medication	<2x/week	>2d/week	Daily	Several times/day
	Interference with normal activity	None	Minor	Some	Extremely limited
	FEV1	>80% predicted; normal between exacerbations		60-80% predicted	<60% predicted
	FEV1/FVC	Normal	Normal	Abnormal	Abnormal
Risk	Exacerbations requiring systematic corticosteroids	0-1x/year	Age 0-4: >2 exacerbations in 6 months; OR >4 wheezing episodes in past year AND risk factors for persistent asthma Age 5-adult: >2 exacerbations per year		
Step Level		Step 1	Step 2	Step 3	Step 4, 5 OR 6 (see Appendix C)
			Modified from DoD/VA CPG, 2010		

APPENDIX B  
ASTHMA CONTROL



<b>Components of Control</b>		<b>Assessing Control</b>	
		<b>Controlled</b>	<b>Not Controlled</b>
Impairment	Daytime Symptoms	<2 times per week	>2 times per week
	Nighttime Symptoms	<2 nights per month	>2 nights per month
	Interference with normal activities	None	Some
	Use of “rescue” medication for symptom control	< 2 times per week	>2 times per week
	Spirometry (predicted)	FEV1 80% AND FEV1/FVC normal	FEV1 <80% OR abnormal FEV1/FVC
	Asthma Control Test score (> 4years old)	>20	<19
Risk	Exacerbation requiring oral corticosteroid	0-1x/year	2x/year
	Progressive loss of lung function	Requires long-term follow-up and regular spirometry (every 1-2 years)	
	Treatment-related adverse events	Medication side effects	
Action		Maintain current therapy; follow-up every 1-6 months; Consider step-down	Step-up therapy; Reevaluate in 2-6 weeks; Consider 5-10 day course of oral steroids if acute exacerbation and reevaluate in 1-2 weeks; Consider referral to specialist
		Modified from DoD/VA (2010)	

APPENDIX C

STEP-WISE APPROACH TO MEDICATION MANAGEMENT

Initial Severity	Use of “rescue” medication	Activity limits	Day Symptoms	Night Symptoms	FEV1	Daily Medication: Preferred	Daily Medication: Alternative
Step 1: Intermittent	<2d/week	NONE	< 2d/week	<2x/month	>80%	SABA prn	--
Step 2: Mild	>2d/week NOT daily	Minor	>2d/week NOT daily	>2x/month	>80%	Low-dose ICS	--
Step 3: Moderate	No more than once a day	Minor	>2d/week NOT daily	>1x/week NOT nightly	60-80%	Age 0-4: Medium-dose ICS OR Low-dose ICS + LTRA	--
						Age 5-adult: Low-Dose ICS + LABA OR Med dose ICS	Low-dose ICS + LTRA
Step 4: Severe	Daily	Some	Daily	Nightly	<60%	Age 0-4: Medium-dose ICS + LTRA	Consider referral to specialist
						Age 5-adult: Medium-dose ICS + LABA	Medium-dose ICS + LTRA
Step 5: Severe	Several times/day	Extreme	Throughout the day	Nightly	<60%	Age 0-4: Medium-dose ICS + LABA + LTRA	Refer to specialist
						Age 5-adult: High-dose ICS + LABA; consider oral corticosteroid	Medium-dose ICS + LABA + LTRA; consider referral
Step 6: Severe	Several times/day	Extreme	Several times/day	Nightly	<60%	Age 0-4: High-dose ICS + LABA + LTRA; consider 5 day course oral corticosteroid	Refer to specialist
						Age 5-adult: High-dose ICS + LABA + oral corticosteroid	High-dose ICS + LABA + LTRA; Refer

APPENDIX D  
ASTHMA ACTION PLAN



## Asthma Action Plan



It is important in managing asthma to keep track of your symptoms, medicines, and peak expiratory flow (PEF).

You can use the colors of a traffic light to help you learn your asthma medicine(s):

**Green means Go,** Do what you want.

**Yellow means Slow,** Take rescue medicine to keep an asthma attack from getting bad, in addition to the controller medicine.

**Red means stop,** Get help from a doctor right now!

**GREEN ZONE MEDICINE:** Doing Well. My breathing is good and I take my regular medicines. No cough, wheeze, chest tightness, or shortness of breath during the day or night.

My Best Peak Flow is: \_\_\_\_\_

Peak Flow Number  
From: \_\_\_\_\_ to \_\_\_\_\_

**80 to 100% of your  
personal best. GO!**

**During Exercise:**

Medicine	How much to take	Time to take it

**YELLOW ZONE MEDICINE:** Asthma is getting worse.

- Cough, wheeze, chest tightness or shortness of breath
- Can do some, but not all, usual activities
- Increased asthma symptoms at night and upon awakening

Peak Flow Number  
From: \_\_\_\_\_ to \_\_\_\_\_  
**50 to less than 80%  
of your personal best.  
CAUTION!**

Add this medicine	How much to take	Time to take it

**RED ZONE MEDICINE:** Medical Alert!

- Trouble walking or talking due to shortness of breath
- Lips or fingernails are blue
- Cannot do usual activities

Peak Flow Number  
From: \_\_\_\_\_ to \_\_\_\_\_  
**50% or less of your  
best. DANGER!**

Add this medicine	How much to take	Time to take it

**Go to the hospital or call the Emergency room (202) 782-1199**

**Patient Identification Stamp:**

**Date:**

**Provider (Stamp/printed):**

**SF600 SUBSTITUTE**

APPENDIX E  
ASTHMA CONTROL TEST

<input type="radio"/> More than once a day (1)	<input type="radio"/> Once a day (2)	<input type="radio"/> 3-6 times a week (3)
<input type="radio"/> Once or twice a week (4)	<input type="radio"/> Not at all (5)	

During the past 4 weeks, how often have you or your child had shortness of breath?

During the past 4 weeks, how often did your or your child's asthma symptoms (wheezing, coughing, shortness of breath, chest tightness, or pain) wake you up at night or earlier than usual in the morning?

<input type="radio"/> 4 or more nights a week (1)	<input type="radio"/> 2-3 nights per week	<input type="radio"/> Once a week
<input type="radio"/> Once or twice	<input type="radio"/> Not at all	

During the past 4 weeks, how often have you or your child used your rescue inhaler or nebulizer medication (albuterol, Xopenex, Maxair, Proventil, Ventolin)?

<input type="radio"/> 3 or more times a day (1)	<input type="radio"/> 1 or 2 times a day (2)	<input type="radio"/> 2-3 times per week (3)
<input type="radio"/> once a week or less (4)	<input type="radio"/> Not at all (5)	

How would you rate you or your child's asthma control during the past 4 weeks?

<input type="radio"/> Not controlled at all (1)	<input type="radio"/> Poorly controlled (2)	<input type="radio"/> Somewhat controlled (3)
<input type="radio"/> Well controlled (4)	<input type="radio"/> Completely controlled (5)	

APPENDIX F  
WAITING ROOM POSTERS





**Do You Have a Child  
with Asthma?**

Does Your Child Have an  
**Asthma Action Plan?**

***If your visit is about Asthma  
related concerns, ask your provider  
about Asthma Action Plans Today!***

For more information about asthma care:  
<http://www.cdc.gov/asthma/parents.html>



APPENDIX G  
PATIENT EDUCATION BOOKLET



*National Capital Military Children's Center*

Asthma is a chronic condition that affects millions of adults and children in the United States. This causes hours of missed work, school and other activities, and costs the healthcare system billions of dollars each year. The real impact is in the health and well being of those affected with the disease.

This booklet was written for our pediatric asthma patients and their families. It should be used as an additional resource – not a substitute – for regular medical appointments.

Dr. Andy Lipton, LTC, MC, USA, Chief, Pediatric Pulmonology  
Dr. H. Stephen Patterson, COL, MC, USA  
Dr. Laura Mulreany, MD  
Jane Jacknewitz-Woolard, CPNP, AE-C  
Charlee Draughn, RN  
HM2 Trina Davenport, RT  
David Smith, BS, RRT

Walter Reed Army Medical Center  
Pediatric Pulmonary Clinic  
(202)782-6101 or (202)782-3405

National Naval Medical Center  
Pediatric Pulmonary Clinic  
(301)295-NAVY or (301)319-8430

Additional resources that may provide information:

Allergy and Asthma Network/Mothers of Asthmatics Inc

[www.aanma.org/](http://www.aanma.org/)

American Academy of Pediatrics (AAP):

[www.aap.org/healthtopics/asthma.cfm/](http://www.aap.org/healthtopics/asthma.cfm/)

Asthma and Allergy Foundation of America (AAFA):

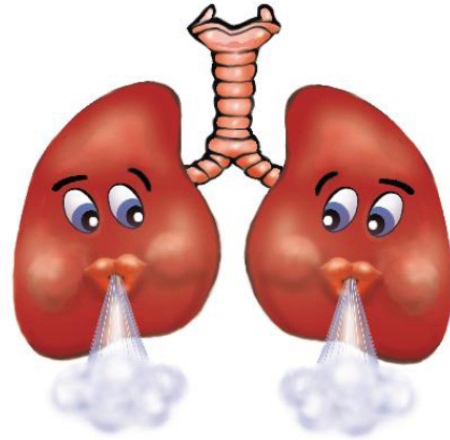
[www.aafa.org/](http://www.aafa.org/)

Kids Health:

[www.kidshealth.org](http://www.kidshealth.org)

## ASTHMA: FACTS TO HELP ME LIVE AND BREATHE

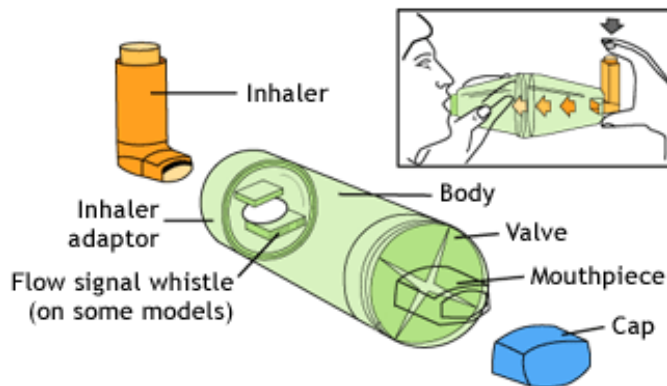
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June 2010

APPENDIX H  
VALVED HOLDING CHAMBER HANDOUT

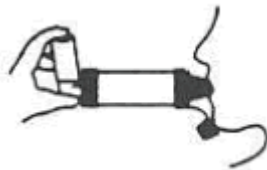
## **SPACER USE**



Spacers should ALWAYS be used with MDIs (Metered-dose inhaler). A spacer is not just for children; it is for people of all ages:)

### **Taking an Inhaled Treatment (WITHOUT MASK):**

1. Shake the inhaler: This mixes the medication properly.
2. Gently breathe out as far as you can, without force, away from the spacer.
3. Put the mouthpiece in your mouth between your teeth and close your lips around it. .

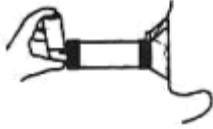


4. Press the inhaler ONCE.
5. Breathe in slowly and deeply over 5 seconds. Slow your breath down if you hear it whistle. If you hear the whistle don't count that puff and try again.
6. Hold your breath for ten seconds. This allows the medication time to deposit in the airways.
7. WAIT ONE MINUTE.
8. Repeat steps 1 - 6 when more than one puff is prescribed.
9. Remember to rinse your mouth after corticosteroid inhalers (Flovent™, Pulmicort™)

### **Taking an Inhaled Treatment (WITH A MASK) Shake canister before each use.**

1. Child should be as calm as possible. Crying will prevent the medicine from making it into the lungs.

- 2.
3. Hold the mask to the face so that both the nose and mouth are covered. It is important to create a good seal between the face and mask so that all medication will be delivered to the airways.



4. Press the inhaler once.
5. Breathe in and out at least 6 to 10 times.
6. Remove the mask from the face. WAIT ONE MINUTE.
7. Repeat steps 1-4 when more than one puff is prescribed.

#### Cleaning and Care for the Spacer.

1. Clean the Spacer twice a month or sooner if needed.
2. Remove the back rubber piece for the spacer.
3. Soak both parts for 15 minutes in lukewarm water with liquid detergent. Move gently in the water. The spacer is not dishwasher safe. Do not use a brush or anything else inside the spacer.



4. Rinse - LEAVE A LITTLE RESIDUE OF DISH SOAP IN THE SPACER!!! – The dish soap coats the inside of the spacer instead of the medicine coating the inside. So, the medicine goes to the lungs☺
5. Shake off excess water but do not rub anything in the spacer. Air dry in vertical position.



APPENDIX I

LETTER OF APPROVAL TO CONDUCT STUDY,  
WALTER REED ARMY MEDICAL CENTER



**DEPARTMENT OF THE ARMY**  
WALTER REED ARMY MEDICAL CENTER  
WALTER REED HEALTH CARE SYSTEM  
WASHINGTON DC 20307-5001

REPLY TO  
23 December 2009

Members on the Committee for the Protection of Human Subjects  
c/o Mr. Ralph Albano, Associate Provost for Research and Director of  
Technology Transfer and Sponsored Research  
The Catholic University of America  
620 Michigan Avenue, NE – Room 213 McMahon Hall  
Washington, DC 20064

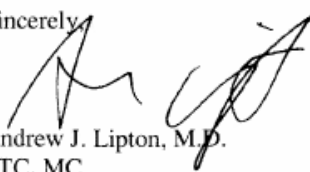
Dear Members of the Committee:

I am writing this letter to notify the Committee for the Protection of Human Subjects that our practice, Pediatric Pulmonology, Walter Reed Army Medical Center, will allow Ms. Jane E. Jacknewitz-Woolard to complete her research study entitled: "Asthma Clinical Practice Guideline Implementation and Evaluation in a Military Treatment Facility Pediatric Clinic" at our service. As indicated in her proposal, asthma a common chronic disease of childhood, yet adherence to current national clinical practice guidelines remains low. Utilization of an evidence-based practice protocol to improve adherence to clinical practice guidelines can result in a dramatic improvement in the quality of life for pediatric asthma patients. This will be beneficial not only to our patients, but also to patients throughout the Department of Defense.

I am further writing this committee to assure you that we will de-identify any patient information (including, but not limited to patient name, patient address, patient identification number, patient insurance number(s), and social security numbers) to protect the identity of all records prior to giving them to Ms. Jacknewitz-Woolard for the conduct of her research study. Further, Ms. Jacknewitz-Woolard has agreed to present any data she obtains in aggregate form.

Should you require additional information, please do not hesitate to contact me. Thank you for your kind consideration in this regard.

Sincerely,



Andrew J. Lipton, M.D.  
LTC, MC  
Chief, Pediatric Pulmonology



APPENDIX J

EXEMPTION CERTIFICATE, THE CATHOLIC UNIVERSITY OF AMERICA,  
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

**CUA**

THE CATHOLIC UNIVERSITY  
OF AMERICA  
*Committee for the Protection of  
Human Subjects (CPHS)*

## EXEMPTION CERTIFICATE

Principal Investigator(s): Jane E. Jacknewitz-Woolard Date: 12/28/09

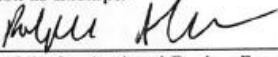
Department(s) Nursing FWA00004459

Title of Study: Asthma Clinical Practice Guideline Implementation and Evaluation in a Military Treatment Facility Pediatric Clinic

The project is exempt under the following category of 45 CFR 46.101:

1. (b) (1) \_\_\_\_\_ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as a) research on regular and special education instructional strategies, or b) research on the effectiveness of or the comparison among instruction techniques, curricula, or classroom management methods.
2. (b) (2) \_\_\_\_\_ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. (b) (3) \_\_\_\_\_ Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior that is not exempt under (2), it: a) the human subjects are elected or appointed public officials or candidates for public office; or b) federal statutes(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. (b) (4) ☒ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. (b) (5) \_\_\_\_\_ Research and demonstration projects which are conducted by or subject to the approval of the department or agency heads, and which are designed to study, evaluate, or otherwise examine: a) Public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes in methods or levels of payment for benefits or services under those programs.
6. (b) (6) \_\_\_\_\_ Taste and food quality evaluation and consumer acceptance studies, a) if wholesome foods without additives are consumed or b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Certification as Exempt:

  
Secretary of the Institutional Review Board (IRB) for  
Research with Human Subjects

1/14/10

Date

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