



Have expert guidelines made a difference in asthma outcomes?

Jenna C. Podjasek^a and Matthew A. Rank^b

Purpose of review

To analyze and summarize research from 2011 to 2012 that examines the relationship of guideline implementation and asthma outcomes.

Recent findings

Evidence of an unmet need for better asthma management was reported in two large survey studies from the US and Europe. Interventional studies of guideline implementation were often limited by lack of uptake of the intervention (i.e. educational program, computer-assisted assessment). Even studies in which there was uptake to the intervention, asthma outcomes often did not improve. Certain interventions (specific electronic asthma management tools, provider education workshops, community-wide interventional programs, and parental educational programs) were associated with improved asthma outcomes. Observational studies, likewise, revealed that evidence of guideline implementation did not necessarily translate into improved asthma outcomes.

Summary

Asthma guideline implementation studies are frequently associated with a limited impact on asthma outcomes. Understanding the gaps between guideline recommendations and translation to clinical practice remains an important opportunity to improve asthma outcomes.

Keywords

asthma, guideline adherence, practice guideline, quality of healthcare

INTRODUCTION

Asthma has emerged as one of the most common chronic diseases in both adults and children. Furthermore, the incidence of asthma and atopy in general has continued to rise with time, particularly in children. Asthma prevalence in the US is estimated to be 8.4% (~25 million individuals affected) [1] and is even higher in some other countries. Numerous randomized controlled trials (RCTs) of specific medication interventions have been performed, allowing increasing confidence in our guideline recommendations. Scientific study focusing on the translation of guidelines into practice, however, has lagged behind as suggested by the ongoing morbidity and mortality associated with asthma worldwide. Outcomes achieved in RCTs are difficult to replicate in practice and interventional studies testing strategies to improve guideline implementation have produced mixed results. In this review, we will summarize the most recent articles (2011–2012) that study the association between guideline implementation and asthma outcomes.

THE EVOLUTION OF ASTHMA GUIDELINES

In 1991, the first guidelines from the National Asthma Education and Prevention Program (NAEPP) were published. These guidelines were formulated in response to growing concern regarding underdiagnosed, untreated or suboptimally treated asthmatic patients in the context of population-based data, suggesting rising asthma morbidity and mortality. In 1993, the National Heart, Lung and Blood Institute (NHLBI), in conjunction with the WHO, published guidelines to address such issues and unify the various approaches to asthma diagnosis and management. Also in 1993, the Global Initiative for Asthma (GINA) was formulated with an

^aDivision of Allergic Diseases, Mayo Clinic, Rochester, Minnesota and
^bDivision of Allergy, Asthma and Clinical Immunology, Mayo Clinic, Scottsdale, Arizona, USA

Correspondence to Matthew A. Rank, MD, 13400 East Shea Boulevard, Scottsdale, AZ 85259, USA. Tel: +1 480 301 4284; e-mail: rank.matthew@mayo.edu

Curr Opin Allergy Clin Immunol 2013, 13:237–243

DOI:10.1097/ACI.0b013e32836093c3

KEY POINTS

- Recent European and US asthma surveys suggest an unmet need for improved asthma management at the population level.
- Studies of asthma guideline implementation frequently fail to change process outcomes.
- Studies of asthma guideline implementation that demonstrate changes in process outcomes frequently fail to demonstrate changes in disease outcomes.
- Recent observational studies suggest that current asthma quality indicators may not be associated with disease outcomes.

emphasis on the standardization of asthma care based on available scientific information. GINA guidelines were subsequently updated in 2002 and 2006. Expert Panel Report (EPR)-2 guidelines from the NAEPP were published in 1997, updated in 2002, and were followed by the most recent EPR-3 guidelines in 2007. The EPR-3 guidelines recommend utilization of a multidimensional system-based approach to asthma management. EPR-3 recommendations also stress the importance of evaluation of current asthma control and assessment of future risk of asthma symptoms. In both the EPR-3 and the 2006 GINA guideline revisions, treatment direction based on current symptom control is emphasized. This is in contrast to prior treatment recommendations centered on treatment of the innate severity of the disease.

ASTHMA OUTCOME MEASURES: DEFINITIONS AND UPDATES

For the purposes of our review, two different types of broad outcome categories can be considered: process outcomes (e.g. increased adherence to guideline recommended medication prescribing, increased use of spirometry, use of the computer-based reminder) and disease outcomes (e.g. quality of life, control, exacerbation rates, mortality). Studies that include both process and outcome measurements are the most informative for this review which is considering the association between guideline implementation and disease outcomes.

There is increasing recognition of the necessity for greater standardization of asthma outcome definitions and assessments. Consistency between asthma measures is essential for comparison of results between studies and for the formation of conclusions based on these results. In 2009, the American Thoracic Society (ATS) published

recommended definitions for asthma exacerbations and outcome measures with a focus on assessment of current symptoms control and future risk [2]. More recently, an expert panel was convened to further address this question [3]. In this article, recommended assessments for core asthma outcomes in specific research designs are outlined in relation to biomarkers, composite scores, exacerbations, healthcare utilization and costs, pulmonary physiology, and quality of life symptoms. This may serve as a guide for future researchers to streamline comparison of results across studies. This important document also notes that further research validating asthma outcome measures are needed, and that caution is warranted when analyzing studies using different types of asthma outcomes.

RECENT POPULATION LEVEL OUTCOME DATA SUGGESTING UNMET ASTHMA MANAGEMENT NEEDS: IMPLICATIONS FOR ASTHMA GUIDELINE IMPLEMENTATION RESEARCH

In a 2009 US survey of 2500 individuals who were above 12 years old, those with asthma were twice as likely to rate their health as only fair, poor, or very poor compared with control individuals without asthma. Sixty-eight percent of individuals with asthma experienced symptoms in the month preceding the survey. Furthermore, in the year preceding the survey, 69% of asthmatic patients reported one or more severe exacerbations [4]. A second study [5] that compared results from the 2009 US survey to a similar survey administered in 1998 concluded that US asthma care and clinical outcomes had changed little from 1998 to 2009. A survey conducted in five European countries in 2006, 2008, and 2010 similarly identified a large group of poorly controlled asthmatic patients [6]. The European survey furthermore identified no significant improved trajectory of asthma control over time, with 55% uncontrolled in 2006, 57% uncontrolled in 2008, and 54% in 2010 (except in Germany where the rate went from 72% in 2006 to 63% in 2010). Taken together, these two large surveys in the US and Europe would suggest a large unmet need for improved asthma management. The results also raise the following important questions: Are these survey results suggesting poor asthma outcomes at the population level due to poor implementation of asthma guidelines? Can improved implementation of asthma guidelines lead to improved asthma outcomes? Which implementation strategies are most effective?

RECENT DATA FROM INTERVENTIONAL TRIALS OF GUIDELINE IMPLEMENTATION

Recent data from interventional trials of guideline implementation are summarized in Table 1. An interventional study [7] implemented a registered nurse-run, system-based asthma management program modeled on GINA guidelines; 2035 adult patients with physician-diagnosed asthma were included. Asthma control was assessed before and after the intervention. Results indicated 29.7 versus 16.5% were found to be uncontrolled before and after the guideline implementation, respectively. Whereas a positive impact of this intervention was detected, we have less confidence in the study design (before and after, patients serve as own controls) than an interventional study with a control group.

A study by Davis *et al.* [8[¶]] assessed the effect of a large-scale comprehensive community approach to asthma diagnosis, management, and education. In this study, 22861 inner city Chicago pediatric patients were included. Multiple educational programs and community outreach programs to address different aspects of asthma control and management were undertaken over a 5-year period. Prescription-inhaled corticosteroids (ICS) dispensing was then compared from the interventional area to all other areas in Chicago. ICS use was considered inadequate if the patient had four short-acting asthma medications dispensed without four or more ICS medications dispensed. Results indicated a significantly higher use of adequate ICS therapy in a subgroup of pediatric patients aged 5–9 for 2 years of the study [odds ratio (OR) 1.30, 95% confidence interval (CI) 1.08–1.55] but no significant difference for patients aged 10–17 years old.

A retrospective study by Shapiro *et al.* [9] in inner city New York compared traditional paper asthma management to an electronic asthma assessment tool (Asthma Toolbox) modeled from NAEPP guidelines. The participants included providers (consisting of general practitioners and registered nurses) caring for 1246 patients. Providers using Asthma Toolbox demonstrated increased documentation of asthma control/severity, emergency department (ED) visits, hospitalizations, and percentage of persistent asthmatic patients on controller medication. Disease outcome measurements were not linked to these improvements in process outcomes in this cross-sectional study.

Guidelines emphasize the importance of collaboration between asthma patients and their providers. They also recommend that patients adopt an active role in the prevention and management of their disease process. Several studies [10,11^{¶¶},12^{¶¶}] have evaluated the impact of patient and parental education on asthma.

Nelson *et al.* [10] selected 247 patients from an urban minority population and randomly assigned them to either 18 months of counseling (mostly phone outreach) or usual care. The intervention group underwent teaching in such areas as asthma home care management, the importance of regular follow-up visits, and the importance of collaboration between the provider and patient. In this study, the number of outpatient care visits increased in the intervention group compared with the control group (80.8 versus 66.9% having at least one outpatient monitoring visit), but asthma ED and hospitalization rates were similar between groups.

Self-monitoring is an important component of patient-centered asthma care. A multicenter RCT study by Ryan *et al.* [11^{¶¶}] looked at the effects of mobile phone versus paper self-monitoring on asthma outcomes. In this study, 288 adolescents and adults were randomly assigned to asthma monitoring via either mobile phones or paper. The electronic monitoring system tracked medication use and peak flow readings and, based on the results, provided feedback for the next step in asthma care. Patients then underwent ACQ and KASE-AQ (knowledge, attitude, and self-efficacy asthma questionnaire) questionnaires. There were no differences in either asthma control or quality of life between the two groups. Furthermore, there were no differences in exacerbations or acute care visits.

A study by Wilson *et al.* [12^{¶¶}] enrolled 519 asthmatic children with a history of tobacco smoke exposure. The effect of counseling and biofeedback using a urinary metabolite of nicotine (cotinine) was correlated with future exposures. Although the overall level of smoke exposure was not different between the intervention and control groups, a subset of patients at increased risk of an acute exacerbation had a significant reduction in smoke exposures ($P=0.017$), but did not have differences for medication use, hospitalizations, and ED visits.

A randomized control trial of 122 providers and 217 patients in Australia evaluated the effect of the Practitioner Asthma Communication and Education (PACE) guidelines on asthma outcomes [13[¶]]. PACE guidelines favor enhanced communication and education between the practitioner, family, and patient. Process outcomes such as a physician-provided written asthma action plan (WAAP), appropriate medication prescriptions, and provider educational skills were significantly increased in the intervention group. Furthermore, patients with mild intermittent symptoms were less likely to be prescribed an inhaled corticosteroid. In this study, outcomes such as exacerbations, control, or quality of life were not assessed.

Table 1. Summary of interventional studies assessing guideline implementation

	Backer <i>et al.</i> (2012)	Davis <i>et al.</i> (2011)	Nelson <i>et al.</i> (2011)	Ryan <i>et al.</i> (2012)	Shah <i>et al.</i> (2011)	Shapiro <i>et al.</i> (2011)	Wilson <i>et al.</i> (2011)
Design	Interventional, not controlled	Interventional, nonrandomized with control group	RCT	Multicenter RCT	RCT	Interventional, noncontrolled	RCT
Intervention	RN administered systematic guideline-based management	Multifaceted community approach involving diagnosis, management and education	Asthma education interventions based on guidelines	Cellular phone asthma monitoring	Provider education workshops (communication and patient education strategies)	Paper or electronic asthma assessment and management tool (Asthma Toolbox), modeled from NAEPP guidelines	Multiple in-person and telephone counseling sessions
Target	Patients, RNs	Patients, physicians, communities	Primary patient caregivers	Patients	GPs, patients	GPs, NPs	Patient caregivers
N	2035	22 861	247	288	122 Providers, 217 patients	1246	519
Practice setting	Academic Primary care	Community Outreach (mobile care van) Primary care	Academic	Community Primary care	Community Primary care	Community Primary care	Academic
Geographic setting	Denmark	Inner city Chicago, IL, US	Urban St Louis, MO, US	UK	Sydney, Australia	Inner city New York City, NY, US	Northern California, US
Process outcomes measured	None	Asthma prescription dispensing data	Outpatient asthma follow-up visits	None	Assessment of Physician provided: WAAP (written asthma action plan), guideline-based prescriptions, and provider teaching/communication skills	Provider documentation of prescribed asthma outcomes	Tobacco smoke exposure
Disease outcomes measured	Asthma control level (based on GINA classification) FEV1	None	ED visits	ACQ	Receipt of WAAP	% of persistent asthmatics on controller medications	Healthcare utilization Controller medication use
Results	Increase in asthma control in intervention group	Higher use of adequate ICS therapy in patients aged 5–9	Increase in outpatient asthma follow-up visits, no difference in ED visits or hospitalizations	No significant difference between groups	The interventional group demonstrated improved medication usage and provider educational skills with a higher % of individuals prescribed a WAAP and spacer device	Significant improvement of provider documentation and the % of persistent asthmatics on controller medication	Subset of patients at high risk of an asthma exacerbation had significantly reduced tobacco exposure following the intervention

Guidelines recommend the use of spirometry in conjunction with the history and physical exam for the diagnosis of asthma. Assessment of asthma control may also be made by spirometry, in concordance with the stepwise asthma approach. A randomized control trial of 397 adults with asthma from 40 different centers in Australia sought to evaluate the impact of spirometry in the primary care setting [14]. The providers were divided into three groups – those that received 6 h of spirometry training, 2 h of spirometry training, or no training. Spirometry was performed upon enrollment in the study, and at 6 and 12 months. There was no significant difference between any of the intervention groups for quality of life, number of days off work due to asthma, and the number of exacerbations. Importantly, the process outcome (obtaining spirometry) in this study had poor uptake in the intervention groups. This is an example of a study in which guideline implementation failed to change the process; thus, disease outcomes would not be expected to change.

RECENT DATA FROM OBSERVATIONAL STUDIES OF GUIDELINE IMPLEMENTATION

Recent data from observational studies of guideline implementation are summarized in Table 2. In 2007, three Children's Asthma Care (CAC) quality core

measures were introduced by the Joint Commission. The first two measures include the use of asthma reliever medications and corticosteroids in pediatric patients hospitalized for an asthma exacerbation. The third measure evaluates whether patients are discharged with a home management plan of care (HMPC). A cross-sectional study of 37 267 patients by Morse *et al.* [15[■]] looked at CAC measure compliance trends and how compliance to these measures affected emergency room visits and hospital readmission rates in children. Overall, the compliance rate for the first two core measures (reliever medication and systemic corticosteroid use) was high. For the third measure, discharge with an HMPC reported compliance rates were 40.6% for the first quarter and 72.9% for the last three quarters of the study. No significant difference was found between HMPC compliance and 7, 30, and 90 hospital day ED visits or readmission rates. Thus, even when a higher proportion of children were discharged with a HMPC, this did not translate into a decrease in asthma exacerbations requiring treatment in an emergency room or hospital.

A prospective cohort analysis of 1426 pediatric asthma patients evaluated the application of seven quality measures modeled from EPR-3 guidelines in patients presenting to the emergency room with an asthma exacerbation [16]. The quality measures

Table 2. Summary of observational studies assessing guideline implementation

	Li <i>et al.</i> (2012)	Morse <i>et al.</i> (2011)	Rank <i>et al.</i> (2012)	Sills <i>et al.</i> (2012)
Design	Retrospective cohort study	Cross-sectional	Cross-sectional	Prospective cohorts
Objective	Evaluate the effect of evidence-based standardized protocols affecting specific asthma outcomes	Determine if an association exists between asthma quality measures and outcomes	Report the change in asthma controller use between two time intervals using the controller-to-total asthma medication ratio Analyze the association to asthma exacerbation rates in the same time period	Investigate the possible association between guideline and outcome measures in acute asthma
Target	ERs	Hospitals	Patients, providers	ERs
N	31 138	37 267	1847	1426
Practice setting	Mixed	Hospital	Mixed	Academic
Geographic setting	Ontario, Canada	Multiple locations in the US	US	Northeast US
Process outcomes measured	Evidence-based standardized protocols	Children's Asthma Care (CAC) adherence trends	Asthma controller-to-total medication ratio > 0.5	7 guideline-based asthma quality measures
Disease outcomes measured	Hospital admission	ED visits	Asthma exacerbation rates	'Successful' discharge
	ER return visit within 7 days	Hospital re-admissions		Symptom resolution
	Hospital follow-up with 7 days			
Results	No significant difference for any outcome	Improved compliance for a home asthma care plan with no differences in ED visits or readmissions	The Asthma controller-to-total medication ratio > 0.5 improved but there were no differences in exacerbation rates	No significant difference for any outcome

included treatment with a short-acting beta agonist, systemic corticosteroids, an inhaled anticholinergic, receipt of a prescription for oral corticosteroids at discharge, and the avoidance of methylxanthines. Other measures tested were receipt of a beta agonist and oral corticosteroid within 1 h of arrival. There was no association between quality measures, symptom relapse, or hospital admission.

A cross-sectional population level study involving 1847 patients by Rank *et al.* [17] evaluated rates of asthma controller medication use over time. Using the outcome measure of controller-to-total asthma medication ratio, asthma exacerbation rates from 1997 to 1998 were compared to rates from 2004 to 2005. The controller-to-total asthma medication ratio is the number of prescriptions given to control asthma symptoms, divided by the total number of prescriptions given for asthma treatment. The controller-to-total asthma medication ratio is a surrogate measure of adherence to asthma medication guideline recommendations and is associated with asthma outcomes. Results of this comparison demonstrated that an increase in the controller-to-total asthma medication ratio did not translate into a decrease in exacerbation rates over this same time period.

A retrospective population-based cohort study by Li *et al.* [18[■]] evaluated the effectiveness of evidence-based standardized protocols on asthma outcomes. This study included 31 138 pediatric patients treated at 146 EDs in Ontario, Canada. Of the 146 EDs, 43 (29.5%) had standardized protocols in place. In comparing the patients treated at EDs with and without standardized protocols, there was no significant difference between hospital admissions, ED return visits or outpatient visits within the first 7 days of initial treatment. Of note, standardized protocols were counted if the ED had a protocol in place, but did not measure if the specific protocol was followed. Therefore, the negative findings could be attributed to physicians not utilizing or following the protocol or patient nonadherence. This study points out the need for additional future studies assessing the link between process and disease outcomes.

CONCLUSION

Expert guidelines are likely influencing asthma outcomes positively, though direct evidence of this influence is often lacking. In our review of recent articles pertaining to the impact of guidelines on asthma outcomes, we found mixed results (some positive and some negative). Studies focused on the translation of asthma guidelines and their impact

on asthma outcomes will continue to be important for optimizing asthma management.

Acknowledgements

None.

Conflicts of interest

Funding disclosure: None.

REFERENCES AND RECOMMENDED READING

Papers of particular interest, published within the annual period of review, have been highlighted as:

- of special interest
- of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 316).

1. Akinbami LJ, Moorman JE, Bailey C, *et al.* Trends in asthma prevalence, healthcare use, and mortality in the United States, 2001–2010. NCHS Data Brief No. 94, May 2012.
 2. Reddel HK, Taylor DR, Bateman ED, *et al.* An official American Thoracic Society/European Respiratory Society statement: asthma control and exacerbations: standardizing endpoints for clinical asthma trials and clinical practice. *Am J Respir Crit Care Med* 2009; 180:59–99.
 3. Busse WW, Morgan WJ, Taggart V, Togias A. Asthma outcomes workshop: overview. *J Allergy Clin Immunol* 2012; 129 (3 Suppl):S1–S8.
 4. Meltzer EO, Blaiss MS, Nathan RA, *et al.* Asthma burden in the United States: results of the 2009 Asthma Insights and Management survey. *Allergy Asthma Proc* 2012; 33:36–46.
 5. Nathan RA, Meltzer EO, Blaiss MS, *et al.* Comparison of the Asthma in America and Asthma Insight and Management surveys: did asthma burden and care improve in the United States between 1998 and 2009? *Allergy Asthma Proc* 2012; 33:65–76.
 6. Demoly P, Annunziata K, Gubba E, Adamek L. Repeated cross-sectional survey of patient-reported asthma control in Europe in the past 5 years. *Eur Respir Rev* 2012; 21:66–74.
 7. Backer V, Bornemann M, Knudsen D, Ommen H. Scheduled asthma management in general practice generally improves asthma control in those who attend. *Respir Med* 2012; 106:635–641.
 8. Davis SQ, Krishnan JA, Lee K, *et al.* Effect of a community-wide asthma intervention on appropriate use of inhaled corticosteroids. *J Urban Health* 2011; 99 (Suppl 1):144–155.
- This interventional study involved a large-scale comprehensive community approach to asthma diagnosis, management and education in urban pediatric patients and was able to demonstrate significantly higher use of adequate inhaled corticosteroid therapy in a subgroup of 5–9-year-olds, but not in 10–17-year-olds.
9. Shapiro A, Gracy D, Quinones W, *et al.* Improving documentation of pediatric asthma management using a decision-making tool. *Arch Pediatr Adolesc Med* 2011; 165:412–418.
 10. Nelson KA, Highstein GR, Garbutt J, *et al.* A randomized controlled trial of parental asthma coaching to improve outcomes among urban minority children. *Arch Pediatr Adolesc Med* 2011; 165:520–526.
 11. Ryan D, Price D, Musgrave SD, *et al.* Clinical and cost effectiveness of mobile phone supported self monitoring of asthma: multicentre randomized controlled trial. *Br Med J* 2012; 344:e1756.
- This multicenter RCT compared mobile phone versus paper self-monitoring and found no important differences in asthma outcomes between the two groups. This study highlights the importance of studying the impact of technology on patient outcomes prior to widespread adoption of unproven technologies.
12. Wilson SR, Farber HJ, Knowles SB, Lavori PW. A randomized trial of parental behavior counseling and cotinine feedback for lowering environmental tobacco smoke exposure in children with asthma. *Chest* 2011; 139:581–590.
- This RCT found that counseling and biofeedback using a urinary metabolite of nicotine (cotinine) reduced smoke exposure in a high-risk subgroup; however, there were no differences in medication use, hospitalizations, and ED visits in any of the groups analyzed. Counseling and biofeedback using cotinine may be a promising approach to reduce tobacco smoke exposure.
13. Shah S, Sawyer SM, Toelle BG, *et al.* Improving paediatric asthma outcomes in primary healthcare: a randomized controlled trial. *Med J Aust* 2011; 195:405–409.
- This RCT found that the Practitioner Asthma Communication and Education guidelines led to an increase physician-provided written asthma action plan, appropriate medication prescriptions, and provider educational skills; outcomes such as exacerbations, control, or quality of life were not assessed.

14. Holton C, Crockett A, Nelson M, *et al.* Does spirometry training in general practice improve quality and outcomes of asthma care? *Int J Qual Healthcare* 2011; 23:545–553.
15. Morse RB, Hall M, Fieldston ES, *et al.* Hospital-level compliance with asthma care quality measures at children's hospitals and subsequent asthma-related outcomes. *J Am Med Assoc* 2011; 306:1454–1460.

This cross-sectional study found that compliance with guidelines to send children home with a home plan of care following hospitalization for asthma had no significant impact on 7, 30, and 90 hospital day emergency department visits or readmission rates. The results from this study call for a re-examination of pediatric inpatient quality measures for asthma.

16. Sills MR, Ginde AA, Clark S, Camargo CA Jr. Multicenter analysis of quality indicators for children treated in the emergency department for asthma. *Pediatrics* 2012; 129:e325.

17. Rank MA, Liesinger JT, Ziegenfuss JY, *et al.* The impact of asthma medication guidelines on asthma controller use and on asthma exacerbation rates comparing 1997–1998 and 2004–2005. *Ann Allergy Asthma Immunol* 2012; 108:9–13.

18. Li P, To T, Parkin PC, *et al.* Association between evidence-based standardized protocols in emergency departments with childhood asthma outcomes: a Canadian population-based study. *Arch Pediatr Adolesc Med* 2012; 166:834–840.

This retrospective population-based cohort study found that having evidence-based standardized protocols for asthma in emergency departments had no significant impact on hospital admissions, ED return visits, or outpatient visits within the first 7 days of initial treatment. This study suggests that simply having evidence-based protocols available for asthma in emergency departments is insufficient to impact key disease outcomes.