The potential of asthma adherence management to enhance asthma guidelines

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Objective: Expert Panel Report 3 Guidelines recommend that physicians use adherence management strategies; however, the evidence for these interventions is weak. Clinicians need effective proven adherence interventions, because approximately 50% of patients with asthma do not follow physician medication recommendations, resulting in unnecessary morbidity. This review examines components of an organized adherence management program that has been successful in uncontrolled trials promoting adherence and reducing morbidity and cost.

Data Sources: Literature review was undertaken in the following areas of asthma management: guidelines, cost; morbidity; adherence, monitoring; and communication skills.

Study Selections: Studies that examined outcomes from psychoeducational, behavioral, monitoring, and communication interventions.

Results: Studies using individual interventions by themselves were modestly effective in promoting adherence. Two uncontrolled studies of children with severe asthma, treated in both inpatient and outpatient rehabilitation settings, used 4 intervention strategies to achieve marked reduction in morbidity and cost. These strategies included: (1) objective adherence monitoring; (2) identification of the cause(s) of nonadherence; (3) delivery of specific strategies for each cause; and (4) use of motivational interviewing communication skills to enhance the delivery of the strategy.

Conclusion: Nonadherence continues to be a significant problem. Physicians need a proven organized approach to improve adherence and reduce morbidity and cost. Evaluation of effective methods in a controlled fashion is warranted to increase adherence management evidence for future asthma guidelines.


INTRODUCTION

The stepwise approach to managing asthma long-term in children and adults per Expert Panel Report-3, (EPR-3)1 requires providers to monitor adherence of symptomatic patients. Clinicians are asked first to check patient adherence, environmental control, and comorbid conditions. Once these have been evaluated and symptoms persist, they are instructed to consider options to step up to a higher level of therapy. The focus of this review article is to examine an asthma adherence disease management model that includes: (1) methods to diagnose adherence status; (2) identification of factors associated with poor patient adherence; (3) strategies that can be used to improve adherence; and (4) communication techniques such as motivational interviewing to enhance the delivery of the strategy(s) selected.

ASTHMA ADHERENCE MANAGEMENT

Extent of Nonadherence with Asthma Recommendations

The EPR-3 recommends that individuals with persistent asthma take 1 or more controller medications daily, use rescue medication as needed for symptoms, monitor lung function with peak flow monitors, and avoid asthma triggers. Adherence rates for inhaled corticosteroids (ICS) range from 44% to 72%. Only 8% to 13% of patients taking ICSs continue to fill their prescriptions 1 year after the initial prescription. Adherence to peak flow monitoring in clinical studies ranges from 64% to 91%, with higher values associated with electronic meters. Adherence to environmental recommendations to decrease exposure to dust mites varies from 27% after conventional instructions to 39% after computer-assisted interventions. Patients’ adherence with avoidance measures is much lower than that with medications, primarily because of the relatively quicker clinical improvement after medications compared with avoidance measures. Nonadherence to medication is associated with increased asthma symp-
PATIENT EDUCATION OFTEN FAILS TO ACHIEVE ADHERENCE

Increasing asthma knowledge through education yields little improvement in patient adherence or asthma outcomes. Interventions that encourage patients to monitor symptoms or peak flow have shown significant but small effects on asthma morbidity. Self-management approaches, including identifying barriers to adherence, self-monitoring medication use, goal setting, and problem solving, result in fewer urgent care visits, short-term improvements in adherence, higher asthma management self-efficacy, improved quality of life, reduced asthma symptoms, and less beta-agonist use. Unfortunately, most self-management studies involve more than 5.5 hours of patient contact. Furthermore, an important limitation of both educational and self-management approaches is that they are predicated on the assumption that patients are motivated to accept treatment recommendations.

ADHERENCE MANAGEMENT MODEL

Adherence management focuses on methods to promote adherence to a prescribed medical regimen. Adherence to recommendations is a necessary component for the treatment plan to be successful. Without adherence, efforts to manage an individual’s disease and obtain desired outcomes are significantly curtailed. The 4 components of adherence management as it relates to the management of chronic asthma include: (1) objectively diagnose patient adherence status; (2) identify risk factors (barriers) associated with patient nonadherence; (3) select strategies appropriate for the risk factors identified; and (4) use effective communication skills such as motivational interviewing (MI). Motivational Interviewing can efficiently enhance the delivery of strategies for patients who are not ready to change behaviors as required for successful asthma management. These techniques can be used in many clinical settings, including the clinic and disease management programs. The overview of this clinical method is presented in Figure 1.

Component 1: Objectively Diagnose Adherence Status

Rationale for monitoring. The EPR 3 Guidelines recommend that the provider evaluate symptomatic patients for reasons for treatment failure before stepping up to stronger therapy. These guidelines include assessing for adherence, evaluating inhaler technique, reviewing implementation of environmental controls, and examining the patient for comorbid conditions. Providers may request laboratory and imaging studies as well as consulting asthma specialists in more difficult cases. An increasing knowledge base documents that many patients who are prescribed anti-inflammatory drugs for metered-dose inhalers (MDIs) do not accurately report ICS medication use to their physicians. This finding has been documented in both adult and pediatric patients by using microchip technology.

The significance of inaccurate patient reporting was demonstrated by Milgrom et al. These investigators evaluated adherence in 24 children with moderate-to-severe asthma who were prescribed an ICS and monitored electronically without their knowledge. Diary card data for the 12-week study showed that parents reported that all doses were taken on a median of 54% of study days and at least 1 dose on a median of 97% of study days. However, electronic records of ICS use showed that these values were actually 5% and 58%, respectively. These children were followed for 3 months. Sixteen children, who each had a median of 70% adherence with the ICS, did not require prednisone for acute symptoms during the 3-month study. Eight subjects required prednisone during the 3 month study to stabilize lung function. The median adherence of this group was 11%. If these investigators had relied on patient/parent diary reports without objective adherence measures, they would have presumed that the 8 subjects who required oral steroids had been taking their
inhaled steroid maintenance medication. In clinical practice, when symptomatic patients overstate medication use, they run the risk of side effects and cost from unnecessary and inappropriate treatment intensification and continued poor asthma control, as well as permitting the true cause of treatment failure, nonadherence, to go unrecognized.21

Although EPR-3 recommends that clinicians assess and encourage adherence during all asthma visits, the evidence for this recommendation is limited in that it is only supported by 2 studies.27,28

The EPR-3 concludes: “Evidence concerning the optimal frequency for assessing and encouraging adherence among asthma patients is lacking, and no evidence from adherence studies identifies any single successful method.” They encourage randomized control trials to be completed, to increase the level of evidence to support this recommendation.29

Methods to Assess Adherence

1. Assays. Effective asthma adherence management requires more than patient history to diagnose adherence status. Table 1 reviews the direct and indirect methods available to measure patient adherence. Direct measures such as blood and saliva measures of theophylline, an oral bronchodilator, were commonly used to evaluate patient adherence in the 1970s and 1980s in the United States before anti-inflammatory medication became the standard of care. Developing assays for leukotriene antagonists to directly diagnose adherence status is possible.21 Medication standards that were used to measure drug levels in pharmacokinetic studies to gain Food and Drug Administra-

Table 1. Assessing Adherence

<table>
<thead>
<tr>
<th>Indirect methods</th>
<th>Direct methods</th>
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<tbody>
<tr>
<td>Question the patient</td>
<td>Observation</td>
</tr>
<tr>
<td>Ask patient to complete questionnaire</td>
<td>Measure levels of a medicine (eg, blood/urine)</td>
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<tr>
<td>Evaluate patient diaries for completeness</td>
<td>Measure biological marker attached to the medicine</td>
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<tr>
<td>Assess adherence based on response to treatment</td>
<td>Conduct unannounced spot checks of patients at home/clinic</td>
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<tr>
<td>Conduct pill counts</td>
<td>Measure clinic attendance</td>
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<tr>
<td>Use electronic monitors for physiologic markers (eg, pulmonary function)</td>
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<tr>
<td>Determine from pharmacy whether prescriptions were filled</td>
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2. Monitors for MDI. Although manufacturers of MDIs are providing counting devices for patients on these new products, these have limited use as adherence monitors because they do not record the date and time of use. Commercially available monitoring devices include the Doser CT (Meditrack Products, Hudson, Massachusetts)
and the SmartInhaler (Nexus6, Auckland, New Zealand). A study comparing the Doser CT with the MDILog (a more sophisticated monitor made by Westmed, Tucson, Arizona that is not currently marketed) found no statistical difference in the accuracy of the Doser CT (94.3%) and the MDILog (90.1%), with the authors concluding that both devices are sufficiently accurate to be used in most clinical settings. A study comparing the accuracy of all 3 electronic monitors found comparable accuracy.

The Doser CT is inexpensive but records only 30 to 45 days of data and does not generate an electronic record for the clinician of date and time of use. The MDILog has the capability of measuring patient inhalation technique, which distinguishes between actuation and actual use, and provides audible feedback; however, the MDILog only fits certain brands of MDI. The SmartInhaler technology can be applied to a greater number of MDIs currently in use. It also provides audible feedback as reminders and includes wireless capability to permit remote monitoring. These assays and devices permit clinicians to determine whether symptoms are secondary to treatment failure versus failure to administer treatment. This knowledge yields more accurate and higher quality of care, reducing morbidity and cost while improving quality of life.

3. Who should be monitored? The EPR-3 includes 5 parameters when evaluating the rationale for assessing and monitoring asthma patients. These are severity of disease, patient control, responsiveness to therapy, patient impairment, and patient risk for persistent symptoms. Risks include the likelihood of asthma exacerbation, progressive decline in lung function, and possibility of adverse effects from medication. High-risk factors for monitoring include patients who: (1) feel endangered or frightened by their asthma; (2) experience psychosocial factors such as depression, increased stress, or socioeconomic factors that limit care; or (3) have attitudes or beliefs that preclude taking medication. These same risk factors for persistent symptoms are also found as risk factors for nonadherence in the 2008 Global Initiative for Asthma (GINA) Guidelines.

4. Efficacy of adherence monitoring. Two studies have demonstrated the effectiveness of monitoring. Onyirimba et al conducted a randomized 10-week trial of 19 adult inner-city women from the lower socioeconomic class. Both groups were monitored for ICS use by the MDILog. During the study, the clinician in one group gave feedback to subjects each week about medication use. The clinician in the nonfeedback group provided the same standard of care but was not aware of medication use. The mean daily adherence in the feedback group was above 70% throughout the study, whereas adherence in the nonfeedback group continued to drop weekly, ending below 30% at the 10th week. This study demonstrated the ability to use monitoring to maintain adequate adherence.

Weinstein et al used theophylline monitoring and psycho-educational interventions for children with severe asthma and their parents, who were initially treated in a short-term inpatient rehabilitation setting (median, 15 days) and followed for 4 years as outpatients. Theophylline was one component of the multiple medications (anti-inflammatory and bronchodilators) that these children were receiving. Theophylline levels were obtained and reviewed at each outpatient visit. Mean theophylline level was 11.0 μg/Dl. Before rehabilitation, the median cost of asthma care was $10,240 per patient; median hospital days, 7; emergency visits, 4. At all 4 years of follow-up, the median number of hospital days and emergency visits for asthma was 0. Costs at 1 year of follow-up were $4,036 and decreased to $1,936 at the end of the fourth year.

The adherence management model was also tested in a smaller group of 11 children treated in an outpatient rehabilitation setting and followed for 1 year. This group had a higher percentage of patients receiving ICSs and referrals from specialists (allergist/immunologists and pulmonologists) than the inpatient study. Despite the shorter length of treatment, the outpatient program had comparable reduction in hospital days, emergency visits for asthma, and costs for asthma care. These studies demonstrated that theophylline monitoring combined with targeted educational and behavioral interventions improved and maintained adherence and reduced morbidity in both inpatient and outpatient settings.

Component 2: Identify Risk Factors for Adherence

In its 2003 Report, the World Health Organization presents an organizational framework to understand the multifactorial causes for nonadherence. The publication describes 5 dimensions/factors that relate to adherence: (1) health system/healthcare providers; (2) social and economic; (3) therapy-related; (4) patient-related; and (5) condition-related. The GINA 2008 Guidelines published management recommendations for providers in 2008 that included identifying risk factors for nonadherence to asthma treatment. The risk factors were organized into drug-related and non–drug-related factors. Establishing the reason for nonadherence is essential when planning an intervention. An intervention for someone who cannot afford treatment is understandably different than it is for one who does not understand the treatment.

The Asthma and Allergy Foundation of America has published on its website an adherence tool, the Asthma Personalized Assessment and Control Tool, which allows patients to self-identify high-risk factors for poor adherence. This tool contains 13 of the 19 risk factors published by GINA 2008 and is presented in an organized format for review by the patient and his or her provider. The GINA risk factors and potential adherence strategies for each are presented in Table 2.

Component 3: Adherence Strategies/Interventions

Strategies to promote adherence may be classified in several ways. Haynes et al identified 3 principal strategies: drug regimen management, educational, and behavioral.
<table>
<thead>
<tr>
<th>Factors affecting adherence</th>
<th>Interventions to improve adherence</th>
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<tbody>
<tr>
<td><strong>Drug-related factors</strong></td>
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<tr>
<td>Difficulties with inhaler devices</td>
<td>Identify appropriate device for patient. Demonstrate use and have patient demonstrate technique in turn.</td>
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<td>Awkward regimens—e.g., 4 times daily—or multiple drugs</td>
<td>Simplify regimen or tailor to patient preference.</td>
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<tr>
<td>Fears about side effects</td>
<td>Determine whether concern is theoretical or specific. If specific, relate the persistence of the symptoms vs likelihood of side effects. Use Motivational Interviewing to assess pros vs cons and reduce ambivalence. Consider referral to support group.</td>
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<tr>
<td>Cost of medication</td>
<td>If patient has prescription plan, select least expensive drug. If not, refer to discount pharmacy plans or pharmaceutical programs.</td>
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<tr>
<td>Dislike of medication</td>
<td>Reduce allergic or irritant exposure to decrease symptoms or medication. Use Motivational Interviewing to discuss “pros and cons” and reduce ambivalence.</td>
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<tr>
<td>Distant pharmacies</td>
<td>Identify capability of receiving prescription by mail.</td>
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<tr>
<td><strong>Non–drug-related factors</strong></td>
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<tr>
<td>Misunderstanding or lack of instruction</td>
<td>If lack of instruction, provide instruction. Assess level of literacy. If low, provide suitable education strategy. Review pathophysiology and rationale for treatment as well as consequences of no treatment. Provide instruction and have patient demonstrate technique.</td>
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<tr>
<td>Dissatisfaction with health care professionals</td>
<td>Have patient speak to administrator regarding issue. May require patient to see another provider if interactions do not improve.</td>
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<tr>
<td>Unexpressed/undisclosed fears or concerns</td>
<td>Identify concerns and address each. Determine whether they are theoretical or actual. Consider referral to a support group. May require psychological intervention if fears or concerns persist.</td>
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<tr>
<td>Inappropriate expectations</td>
<td>Clarify expectations from a medical perspective. If patient expects greater or quicker improvement, attempt to reset expectations. Review role of allergen/irritant exposure as factor.</td>
</tr>
<tr>
<td>Poor supervision, training, or follow-up</td>
<td>Encourage supervision for children/elderly. Review use of medication in office. Schedule appropriate follow-up.</td>
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<td>Anger about condition or its treatment</td>
<td>Identify reason for anger. Express that treatment may improve condition. Assess ambivalence about treatment and review possible alternatives.</td>
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<tr>
<td>Underestimation of severity</td>
<td>Relate symptoms with pulmonary function or use exercise challenge to demonstrate severity of condition.</td>
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<tr>
<td>Cultural issues</td>
<td>Appreciate that varying cultures have different concepts of development of asthma, factors that exacerbate it, and treatment choices. Take advantage of community health workers to clarify issues.</td>
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<tr>
<td>Concerns about stigmatization</td>
<td>Assess patient reaction to diagnosis. Understand the patient’s concerns and refer to support group if the concerns persist.</td>
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<tr>
<td>Forgetfulness or complacency</td>
<td>Determine whether the problem is forgeting to follow treatment vs other reasons. Consider tailoring medication use to patient’s daily activities.</td>
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<tr>
<td>Address complacency by withdrawing treatment to determine actual need for treatment.</td>
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<tr>
<td>Attitudes toward ill health</td>
<td>Assess patient’s health beliefs about asthma and treatment. For patients who question the diagnosis or efficacy of treatment, consider stopping treatment and having patient monitor lung function at home.</td>
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<tr>
<td>Religious issues</td>
<td>Clarify how patient’s religious beliefs may affect attitudes about diagnosis and treatment. Discussing this with patient’s religious leader may give insight and source of support for the patient.</td>
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</table>

*b Guidelines for the Diagnosis and Management of Asthma (EPR3) 2007. NIH, NHLBI. August 2007. NIH publication no. 08-4051.
Another approach may be to examine different types of nonadherent behaviors and select interventions accordingly. Rand et al\textsuperscript{42} describe 3 forms of nonadherent behaviors: erratic, unwitting, and intelligent.

Erratic patients have difficulty following treatment because of the complexity of treatment or the chaos of their lives. They tend to be forgetful, to be too busy with changing schedules, and frequently run out of medication. Their priorities do not match the requirements to follow the regimen recommended by their provider. Strategies for this group include simplifying the regimen, tailoring medication administration to daily activities of the patient, and using memory aids such as pill organizers. Unwitting patients misunderstand the dosing regimen or forget instructions. They fail to understand the rationale for therapy and do not distinguish acute from preventive therapies. There may be language barriers or health literacy issues.

The strategy for this group is to identify the specific adherence dosing error of the patient and then provide educational programs with written or visual medication plans. Intelligent patients frequently believe that they know more about the appropriate treatment than the provider does. They may say that they do not need treatment or it is ineffective; they are concerned about drug dependence, side effects, or addiction; or they have a different cultural belief from the provider. These individuals would be candidates for education and counseling and may require negotiation as well as linking therapy with personal goals. Despite the reports of effectiveness of noncontrolled intervention studies to improve adherence, randomized controlled adherence studies from multiple disease states have failed to demonstrate long-term gains in promoting adherence and reducing morbidity. McDonald et al\textsuperscript{43} reviewed 39 controlled adherence studies from primarily multiple chronic diseases (diabetes, arthritis, epilepsy, asthma, and mental health disorders) and found that only 19 of 39 were associated with significant increases in medication adherence and 17 of 39 reported significant improvement in treatment outcomes.

McDonald et al\textsuperscript{43} suggested that the current methods of improving medication adherence for chronic health are not predictably effective and tend to be complex and labor-intensive. These authors believe that “the full benefits of medications cannot be realized at currently achievable levels of adherence; therefore, more studies of innovative approaches to assist patients to follow prescriptions for medications are needed.”\textsuperscript{43} Medication adherence monitoring may be such an “innovative approach”; however, randomized control studies need to be conducted to test this hypothesis.

**Component 4: Enhancing Communication**

A meta-analysis of adherence studies for multiple chronic conditions examined the relationship between patient adherence and clinician communication behaviors. Greater adherence to recommendations occurs when clinicians ask about adherence to treatment; are less critical, negative, or angry; are supportive and understanding; and are nonjudgmental.\textsuperscript{44}

Dimatteo\textsuperscript{45} reports that patients respond to clinicians who respect and support patient concerns, elicit feelings and concerns, respond to requests for information, place the patient in a more active role for care, and fulfill patient expectations.

Stewart et al\textsuperscript{46} described specific patient-centered clinician behaviors and actions to improve outcomes and satisfaction. These include actively assessing the patient’s world, building rapport, finding common ground, and identifying motivational readiness. Specifically, the clinician identifies the extent or severity of the disease; determines how the illness limits patient activity or affects quality of life; and assesses motivational readiness (ie, whether the patient understands the importance of following the plan and has the confidence to do so).

Patient-centered approaches are associated with better patient retention and treatment outcomes, without increased time and cost.\textsuperscript{47–49} MI is a patient-centered counseling approach that can be briefly integrated into patient encounters and is specifically designed to enhance motivation to change among patients otherwise not ready to change.\textsuperscript{19}

Existing asthma management approaches (eg, education and self-management) increase resistance among patients not ready or willing to follow medical recommendations. MI helps patients resolve their ambivalence about behavior change and builds their intrinsic motivation before providing education.\textsuperscript{50} Although MI overlaps with patient-centered communication, it additionally includes some concrete motivational strategies that can be briefly and easily implemented in medical settings (eg, negotiating a treatment plan, assessing motivation and confidence for change, helping the patient weigh the costs and benefits of change, and providing medical advice and health feedback).\textsuperscript{51} Reflective listening is used to help patients clarify their ambivalence and defuse resistance.\textsuperscript{51} MI technique has been shown to be efficacious across a wide variety of health behavior change areas.\textsuperscript{52–55}

A recent controlled study applied shared treatment decision making, a form of patient-centered health care, to the management of adult asthma patients.\textsuperscript{56} Some of the counseling techniques of shared decision making that were used in the study are similar to those used in MI (establish rapport; identify patient goals and preferences; evaluate “pros and cons” of treatment plan; negotiate a decision about treatment regimen). Study subjects, however, were not given feedback about medication use. The experimental group had significantly better clinical outcomes (asthma-related quality of life, healthcare use; rescue medication use, asthma control, and lung function) and enhanced adherence. Determining whether adherence monitoring used in conjunction with shared decision making would

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achieve superior results to shared decision making alone would be of interest.

APPLICATION IN DISEASE MANAGEMENT
As posted on the Disease Management Association web site, disease management has been defined as a process that: (1) supports the physician or practitioner/patient relationship and plan of care; (2) emphasizes prevention of exacerbations and complications, using evidence-based practice guidelines and patient empowerment strategies; and (3) evaluates clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health. Disease management components include: (1) population identification processes; (2) evidence-based practice guidelines; (3) collaborative practice models to include physician and support-service providers; (4) patient self-management education (may include primary prevention, behavior modification programs, and compliance/surveillance); (5) process and outcomes measurement, evaluation, and management; and (6) a reporting/feedback loop (may include communication with patient, physician, health plan, and ancillary providers, and practice profiling).

Schrijvers has expanded the definition by emphasizing the importance of the use of modern health information technology. Technology facilitates communication between professionals in a disease management program and integrates all data in one electronic patient record, to support telemedicine and management. With technology, disease management companies can: (1) identify adherence by using electronic monitors or prescription refill data; (2) evaluate pulmonary function and patient diary remotely; (3) use web-based applications for telemonitoring, as well as to provide feedback and reminders to professionals and patients; and (4) deliver adherence strategies with optimal communication techniques via telephone to motivate patients to follow an effective treatment plan. Increased focus on adherence management will enhance the quality of care for patients (Table 2).

Asthma Adherence Management Improves Quality Control
The term Six Sigma refers to a successful business strategy applied by Motorola USA in 1981 to decrease the number of defective microchips to 3.4 per million occurrences. Managers developed a “Process Improvement” plan to eliminate the root causes of performance deficiencies that existed in the organization, using the following 5-step approach: (1) Define and identify serious problems and allocate resources to solve the problem; (2) Measure data that accurately describe how the process should work; (3) Analyze and develop theories as to what might be causing the problem; (4) Improve the root causes by designing and implementing changes to the offending process; (5) Control; ie, design and implement new controls to prevent the original problem from recurring.

Six Sigma has been applied to other manufacturing processes and organizations as well as the organization of care in health care systems. The focus of these health care initiatives is primarily on the organization of care. Asthma adherence management uses the Six Sigma method by providing a systematic approach for the provider to promote adherence. This clinical method: (1) defines adherence (medication level, electronic monitor data, questionnaire response, and so forth); (2) measures adherence; (3) analyzes various reasons for nonadherence; (4) improves adherence by addressing root causes and implementing strategies to promote adherence; and (5) controls for positive outcomes by measuring adherence not only of symptomatic patients but also earlier diagnosed nonadherent individuals.

CONCLUSION
This paper addresses a frequent clinical problem that is difficult to assess and treat unless the clinician has the appropriate tools and strategies. Objective measurement of adherence to medication is a key component, because patients are not always truthful with their medication use. The next steps are to identify the reasons why the patient has had difficulty following the recommended plan and then implement the specific strategy for each cause. MI technique is one of several patient-centered counseling methods to address patient ambivalence about treatments and optimize the delivery of the selected strategy. Asthma adherence disease management has been demonstrated to be effective in uncontrolled trials of children with severe asthma to prevent emergency visits and hospitalizations. A controlled clinical trial is encouraged. If successful, physicians would have an organized method to diagnose and treat nonadherent patients.

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REFERENCES


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