Adult Asthma Disease Management: An Analysis of Studies, Approaches, Outcomes, and Methods

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BACKGROUND: Disease management has been implemented for patients with asthma in various ways. We describe the approaches to and components of adult asthma disease-management interventions, examine the outcomes evaluated, and assess the quality of published studies. METHODS: We searched the MEDLINE, EMBASE, CINAHL, PsychInfo, and Cochrane databases for studies published in 1986 through 2008, on adult asthma management. With the studies that met our inclusion criteria, we examined the clinical, process, medication, economic, and patient-reported outcomes reported, and the study designs, provider collaboration during the studies, and statistical methods. RE-SULTS: Twenty-nine articles describing 27 studies satisfied our inclusion criteria. There was great variation in the content, extent of collaboration between physician and non-physician providers responsible for intervention delivery, and outcomes examined across the 27 studies. Because of limitations in the design of 22 of the 27 studies, the differences in outcomes assessed, and the lack of rigorous statistical adjustment, we could not draw definitive conclusions about the effectiveness or cost-effectiveness of the asthma disease-management programs or which approach was most effective. CONCLUSIONS: Few well-designed studies with rigorous evaluations have been conducted to evaluate disease-management interventions for adults with asthma. Current evidence is insufficient to recommend any particular intervention. Key words: asthma, disease management, outcomes, study design, study quality. [Respir Care 2009;54(7):878-886. © 2009 Daedalus Enterprises]

Introduction

Asthma is a chronic disease with substantial morbidity if poorly controlled, and an estimated mortality of 1.3 per100,000 people in 2004. In 2004, 14.3 million adults and 6.2 million children in the United States were reported to have asthma, and had 14.6 million out-patient visits, 1.8 million emergency-department visits, and 497,000 hospitalizations attributed to asthma. Asthma-related healthcare costs were estimated to be \$11.5 billion in direct costs and \$4.6 billion in indirect costs, which included 11.8 million lost work days for adults and 14.7 million missed school days for children.

Disease-management programs have been implemented by health-maintenance organizations, pharmacy-benefit-management firms, and Medicaid agencies to enable better asthma control by supporting the practitioner/patient relationship and a plan of care to prevent exacerbations and complications. Clinical practice guidelines and most disease-management interventions for asthma patients include patient education in individual or group settings to teach patients how to assess peak expiratory flow (PEF), appropriate inhaler technique, and how to independently make treatment modifications in response to symptom changes. Disease-manage-

ment interventions for asthma care differ in the types of providers (physicians, nurses, pharmacists, social workers) involved in intervention delivery and the extent of provider collaboration during and between office visits. Asthma disease-management interventions may also include provider education, risk assessment, monitoring, outcomes analysis, urgent-care support, and feedback mechanisms.^{4,5}

The extent to which the various providers collaborate during and between office visits to support patient self-

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management informs whether asthma care is based on a case-management model, a coordinated-care model, or a multidisciplinary-care (also known as a shared-care) model.^{6,7} In a case-management model, a nurse, pharmacist, or social worker provides urgent-care support and assists patients as a case manager between office visits.^{6,7} In a coordinated-care model, physicians and a nurse or pharmacist jointly develop treatment plans that are reinforced between office visits by the nurse or pharmacist.⁷ In a multidisciplinary-care model, patients are seen during office visits by a care team typically comprising a physician,

a nurse, and possibly a pharmacist, who exchange information on the patient's medical history, current condition, medications, and other relevant details, and jointly develop a treatment plan.⁷ The nurse or pharmacist supports patient self-management between office visits via shared decision making with physicians.

Prior studies have examined the effectiveness of education programs and self-management for asthma, 8.9 but it is not yet clear which disease-management interventions are most effective. The objective of this review is to systematically describe the approaches to and components of asthma disease-management interventions for adults, to examine the outcomes evaluated, and to assess the quality of published experimental and quasi-experimental studies. If it is possible to identify which adult asthma disease-management approaches are most effective, we could establish an evidence base to support implementation of those approaches.

Methods

We searched the MEDLINE, EMBASE, CINAHL, PsychInfo, and Cochrane databases with the following terms from the National Library of Medicine's medical subject headings: asthma, managed care programs, disease management, case management, patient care team, and comprehensive health care. We restricted the search to items in English that were published between January 1986 and July 2008. We screened the abstracts with the following inclusion/exclusion criteria to determine which publications to review in full. A study was excluded if the intervention was strictly patient education or self-management, if the interventions were provided on an in-patient basis, or if the target population included only children. We included 4 types of study: randomized controlled trial (RCT); before/after observational study with a control group; after-only observational study with a

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control group; and before/after observational study without a control group. We chose these 4 study designs because the internal validity of observational evidence is strongest when a study has 2 outcome measurements (either before/after observations on the same subjects, or treatment and control subjects in the after period).

We abstracted information about the study design, the components of and approaches to disease-management intervention, the providers responsible for delivering the interventions, patient risk status, sample size, and 5 types of patient outcomes: clinical, medication, process, economic, and patient-reported outcomes. The abstracted intervention content included whether the study provided patient-education sessions, educational materials, provider-education sessions, provider feedback, assessment and monitoring of patients, or an action plan for patients. Patient risk status was assigned on the basis of each study's description of the patients' asthma severity or patient risk for uncontrolled asthma or an exacerbation. Clinical outcomes included symptoms, PEF, and forced expiratory volume. Medication outcomes included use of various asthma drugs such as inhaled corticosteroid, β agonist, and theophylline. Process outcomes included use of a peak-flow meter, use of an action plan, inhaler technique, and medical record documentation. Economic outcomes included out-patient visits, emergency-department visits, hospitalization, and overall cost. Patient-reported outcomes included asthma-related quality of life, health-related quality of life, days of work/school missed, and patient knowledge and satisfaction.

To assess whether asthma disease management was associated with improved outcomes, we reported the number of times that each type of patient outcome was assessed and the number of times that statistically significant results favoring disease management were found. We also examined whether the significance of patient outcomes varied by study design, to assess the impact of study design on the strength of the evidence for asthma disease management. Lastly, we examined the quality of the study designs (randomization, a control group, 2 or more measurements per subject, sample size), the clarity and completeness of the intervention description (providers involved, collaboration during and between study visits, content of intervention), and the extent of statistical adjustment.

Approval from the University of North Carolina institutional review board was not required because the study analyzed historical data that included no patient-identifiable information, so the study did not constitute human-subjects research as defined under federal regulations.

Results

Our search identified more than 2,000 citations, based on the National Library of Medicine's medical subject headings, and we retained 186 abstracts for further review (Fig. 1). A

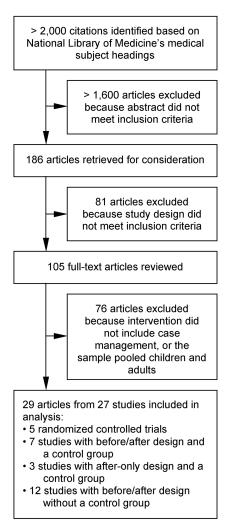


Fig. 1. Screening, exclusion, and inclusion of studies for the present analysis.

study was excluded if the study subjects were children, patient education was the only intervention, the study was conducted in an in-patient setting, or the article was an opinion piece that did not examine a particular intervention. Eightyone abstracts were excluded because the study design was not one of our 4 selected study designs. After screening the abstracts we retrieved and carefully reviewed the full text of 105 studies, 76 of which we excluded because the intervention was education only (n = 22) or self-management only (n = 32), the study pooled children and adults (n = 4), or the study did not report outcomes in sufficient detail (n = 18). Twenty-nine articles that described 27 unique asthma disease-management interventions satisfied our inclusion criteria. Two of the 29 studies presented results from the same intervention, 10,11 and 2 others presented results from another intervention. 12,13

Of the 27 included studies: 5 were RCTs, 14-18 7 were before/after observational studies with a control group; 12,13,19-24

12 were before/after observational studies without a control group;^{10,11,25-35} and 3 were after-only observational studies with a control group³⁶⁻³⁸ (see Fig. 1 and Table 1).

Fourteen studies were conducted in the United States, ^{10,11,14,17-21,23,32-34,36,37} 4 were in the United Kingdom, ^{15,25-27} 2 were in Sweden, ^{31,38} and the remaining 7 were in the Netherlands, Canada, Denmark, New Zealand, Australia, Germany, and Taiwan. ^{12,13,16,22,24,28,29,35} Three studies enrolled low-risk (mild-to-moderate asthma) patients. ^{20,24,31} Eleven studies enrolled higher-risk (moderate-to-severe asthma) patients. ^{12-15,17,19,26,27,30,32,33,36} Five studies enrolled a broad spectrum of patients. ^{10,11,18,22,35,37} Eight studies did not report patient risk. ^{16,21,23,25,28,29,34,38}

The disease-management interventions included: education sessions for patients and/or providers; educational materials for patients; action plan; assessment and monitoring of patients; and feedback to physicians about the patient's health, the need for an office visit, and suggested medication changes (see Table 1). Patient-education sessions were a key component of the interventions in almost every study. The second most common intervention component was assessment and monitoring of patients by the nurse or pharmacist involved in case management. Fourteen studies mentioned that physicians received feedback on their patients. 10,11,14,16-19,23,25,26,30,32,34,35,37 Eleven studies mentioned that an action plan was developed for patients. 14,16,17,23,25,26,28-30,32,38 Nine studies mentioned that educational materials were provided to the patient. 10,11,16,17,19,20,26,27,30,37 Five studies indicated that physicians participated in education sessions to update them on clinical guidelines. 10,11,23,24,30,32 Eleven studies used in-person contact as the means of intervention, 12,13,16,22,24-26,28,29,31,34,38 6 studies solely used telephone contact, 14,18,20,21,23,37 and 10 studies used in-person and telephone contact interchangeably. 10,11,15,17,19,27,30-33,37

The non-physician providers involved in intervention delivery differed markedly across the studies. A nurse was involved in intervention-delivery in 9 studies. 16,19,25,26,30,32,34,36,37 A nurse trained in asthma or respiratory care was involved in 8 studies. 14,15,20,23,27,31,35,38 A pharmacist was involved in 2 studies.^{22,33} A pharmacist trained in asthma care was involved in 2 studies. 12,13,28 A case manager of unspecified training was involved in 3 studies.^{17,21,29} In 2 studies, a nurse and pharmacist worked together, 10,11,16 and a nurse and physician's assistant worked together.24 One study used automated telephone calls to monitor patients and gather information.¹⁸ Nearly all the studies clearly described the content of the disease-management intervention and the providers involved in intervention delivery. However, few studies provided clear descriptions of the extent of collaboration between physicians and non-physician staff during patient office visits (4 studies^{14,18,24,30}) or between patient office visits (1 study²⁷). To understand what type of disease-management model best served the needs of lower-risk and higher-

DISEASE MANAGEMENT IN ASTHMA

e 1. Summary of Studies

First Author	Year	Study Design	Sample Size (treatment/ control)	Country	Intervention in Treatment Group	Intervention in Control Group	Patient Risk	Outcomes Examined	Type of Patient Contact and by Whom
Buchner ¹⁰ Groban ¹¹	1998	Before/after without control group	869'9	United States	Physician education, feedback to physician, education sessions, education materials	Usual care	Mild to severe	Medications - 1 Process - 1 Economic - 5 Patient-reported - 5	In person or telephone by nurse and/or pharmacist
Castro ¹⁴	2003	Randomized controlled trial	50/46	United States	Feedback to physician, education sessions, action plan, assessment and monitoring	Usual care	Moderate to severe	Economic - 7 Patient-reported - 1	Telephone by asthma nurse
Charlton ²⁶	1991	Before/after without control group	115	United Kingdom	Education sessions, education materials, action plan, assessment and monitoring, feedback to physician	Usual care	Moderate to severe	Medications - 2 Economic - 1 Patient-reported - 1	In person by nurse
Charlton ²⁵	1992	Before/after without control group	105	United Kingdom	Education sessions, action plan, feedback to physician, assessment and monitoring	Usual care	Unknown	Clinical - 3 Economic - 1 Patient-reported - 4	In person by nurse
Delaronde ¹⁹	2002	Before/after with control group	40/88	United States	Education sessions, education materials, feedback to physician, assessment and monitoring	Education sessions, education materials, assessment and monitoring	Moderate to severe	Medications - 1	In person or telephone by nurse
Delaronde ²⁰	2005	Before/after with control group	19/19	United States	Education sessions, assessment and monitoring, education materials	Education materials	Mild-to-moderate	Medications - 1 Economic - 3 Patient-reported - 1	Telephone by asthma nurse
Dickinson ²⁷	1997	Before/after without control group	173	United Kingdom	Education sessions, education materials, assessment and monitoring	Usual care	Moderate to severe	Clinical - 1 Medications - 2 Process - 2 Patient-reported - 1	In person or telephone by asthma nurse
Emmerton ²⁸	2003	Before/after without control group	100	New Zealand	Education sessions, assessment and monitoring, action plan	Usual care	Unknown	Patient-reported - 2	In person by asthma pharmacist
Herborg ^{12,13}	2001	Before/after with control group	264/236	Denmark	Assessment and monitoring, education sessions	Usual care	Moderate to severe	Clinical - 2 Medications - 7 Process - 1 Economic - 6 Patient-reported - 5	In person by asthma pharmacist or physician
Hopman ²⁹	1999	Before/after without control group	31	Canada	Education sessions, assessment and monitoring, action plan	Usual care	Unknown	Clinical - 1 Economic - 2 Patient-reported - 1	In person by case manager
Johnson ²¹	2003	Before/after with control group	522/209/592	United States	Education sessions, assessment and monitoring	Usual care	Unknown	Economic - 4	Telephone by case manager

DISEASE MANAGEMENT IN ASTHMA

In person or telephone In person by physician In person or telephone In person or telephone In person or telephone by respiratory nurse In person or telephone In person or telephone In person or telephone In person by asthma Type of Patient Telephone by nurse by case manager and by Whom by asthma nurse by physician or by physician or pharmacist by nurse or nurse nurse Patient-reported - 2 Patient-reported - 3 Patient-reported - 2 Patient-reported - 2 Patient-reported - 2 Patient-reported - 1 Medications - 2 Outcomes Examined Medications - 3 Medications - 4 Medications - 1 Medications - 1 Economic - 11 Economic - 6 Economic - 5 Economic - 2 Economic - 3 Economic - 3 Economic - 1 Economic - 2 Economic - 4 Economic -Clinical - 4 Process - 3 Process - 6 Clinical - 3 Process - 6 Process - 4 Process - 3 Process - 1 Clinical - 1 Clinical - 1 Clinical- 3 Process - 2 Mild-to-moderate Patient Risk Mild to severe Moderate to Moderate to Moderate to Moderate to Moderate to Moderate to Unknown Unknown severe severe severe severe severe education materials, Intervention in Control Group Education sessions, action plan Usual care Jsual care Usual care Education sessions, education Education sessions, education Education sessions, education action plan, assessment and assessment and monitoring, assessment and monitoring assessment and monitoring assessment and monitoring assessment and monitoring physician, assessment and monitoring, feedback to Education sessions, action Education sessions, action materials, feedback to feedback to physician, materials, feedback to physician, action plan materials, action plan, feedback to physician Intervention in Freatment Group plan, assessment and plan, assessment and physician, physician education materials, education sessions, Physician education, Education sessions, Education sessions, Education sessions, Education sessions, monitoring monitoring monitoring education United States United States United States United States United States United States Kingdom Country Australia Sweden Sweden United Sample Size (treatment/ 196/196 740/740 103/108 control) 20/132 3,486 71/82 31/31 317 63 25 Summary of Studies (Continued) Before/after without Before/after without Before/after without Before/after without controlled trial controlled trial controlled trial After-only with control group control group After-only with control group control group After-only with control group control group control group Study Design Randomized Randomized Randomized 1999 2004 2000 2002 1995 2005 2007 2000 2004 2006 Year Lindberg³⁸ Lindberg³¹ Johnson³⁶ First Author Johnson³⁷ Jowers³⁰ Schatz¹⁷ Pilotto¹⁶ Fable 1. Pauley³³ Patel³² Levy¹⁵

e 1. Summary of Studies (Continued)

First Author	Year	Study Design	Sample Size (treatment/ control)	Country	Intervention in Treatment Group	Intervention in Control Group	Patient Risk	Outcomes Examined	Type of Patient Contact and by Whom
Schulz ²²	2001	2001 Before/after with control group	101/63	Germany	Education sessions, assessment and monitoring	Usual care	Mild to severe	Clinical - 4 Process - 1 Patient-reported - 4	In person by physician or pharmacist
Sidorov ³⁴	2002	2002 Before/after without control group	396	United States	Education sessions, feedback to physician, assessment and monitoring	Usual care	Unknown	Economic - 1 Patient-reported - 1	In person by nurse
Steuten ³⁵	2006	2006 Before/after without control group	859	Netherlands	Assessment and monitoring, feedback to physician	Usual care	Mild to severe	Clinical - 3 Economic - 1 Patient-reported - 3	In person by respiratory nurse
Tinkelman ²³		2004 Before/after with control group	258/446	United States	Physician education, education sessions, feedback to physician, action plan	Usual care	Unknown	Economic - 1	Telephone by respiratory nurse
Vollmer ¹⁸	2006	2006 Randomized controlled trial	3,367/3,581	United States	3,367/3,581 United States Feedback to physician, assessment and monitoring	Usual care	Mild to severe	Clinical - 3 Medications - 3 Economic - 3 Patient-reported - 6	Automated telephone
Weng ²⁴	2005	2005 Before/after with control group	1,067/4,340 Taiwan	Taiwan	Physician education, education sessions, assessment and monitoring	Usual care	Mild-to-moderate Economic - 4	Economic - 4	In person by physician, nurse, or physician assistant

Table 2. Study Designs and Outcomes Considered in 27 Studies of Asthma Disease Management*

	Randomized Controlled Trial $(n = 5)$		Before/After Study With Control Group $(n = 7)$		After-Only Study With Control Group $(n = 3)$		Before/After Study Without Control Group (n = 12)	
Outcome Type	Assessments (n)	Statistically Significant Effects (n)	Assessments (n)	Statistically Significant Effects (n)	Assessments (n)	Statistically Significant Effects (n)	Assessments (n)	Statistically Significant Effects (n)
Clinical	8	3	6	2	3	3	12	8
Medication	5	1	9	4	8	4	6	6
Process	6	4	2	2	15	4	7	6
Economic	17	6	18	8	21	12	21	19
Patient-reported	12	2	10	8	2	1	23	11
Total	48	16	45	24	49	24	69	50

^{*} Each cell represents the total number of assessments of that outcome type relative to that study design, which can exceed the number of studies that examined that outcome type, because some studies assessed more than one indicator.

risk adults with asthma, it would be helpful if future studies would provide that detail.

The 27 included studies assessed a wide range of patient outcomes, including clinical, medication, process, economic, and patient-reported outcomes. Eleven studies examined clinical outcomes via 9 clinical measures, for a total of 31 assessments (see Table 1).12,13,15-18,22,25,27,29,31,35,38 The most frequently examined clinical outcomes were symptoms (12 assessments), PEF (4 assessments), and forced expiratory volume (4 assessments). Fourteen studies examined medication outcomes, via one or more of 10 medication measures, for a total of 31 assessments. 10-13,17-20,26,27,30,36-38 The most frequently examined medication outcomes were oral steroids (5 assessments), inhaled corticosteroids (7 assessments), and β agonists (7 assessments) (see Table 1). Eleven studies examined process of care, via one or more of 17 measures, for a total of 34 assessments. 10-13,15,16,22,27,31,32,36-38 The most frequently examined process outcomes were inhaler technique (4 assessments), use of a peak-flow meter (3 assessments), and use of an action plan (3 assessments). Twenty-three studies examined economic outcomes, via one or more of 14 measures, for a total of 84 assessments (see Table 1).10-18,20,21,23-26,29-38 The most frequently examined economic outcomes were emergency-department visits and hospitalization (17 and 19 assessments). Nineteen studies examined patient-reported outcomes, via one or more of 11 measures, for a total of 50 assessments. 10-18,20,22,25-31,34,35,38 The most frequently examined patient-reported outcomes were asthma-related quality of life (11 assessments) and days of work/school missed (9 assessments). Given the range of measures used within each outcome, the limited number of RCTs and inconsistency in reporting means and standard deviations, it was not possible to characterize the significance of results via standardized effect sizes.

There were important differences in patient outcomes by study design (Table 2). Across all outcomes, the study design least subject to observed confounding, unobserved confounding, and regression to the mean (RCT) had the lowest proportion of outcomes that improved in response to disease management. Three trials found no significant improvements associated with disease management. 16-18 In the other 2 trials the interventions reduced out-patient visits in the patients randomized to disease management,14,15 and one trial also improved appropriate use of inhaled steroids and rescue medication and PEF.15 The study design most subject to observed and unobserved confounding (before/after observational study without a control group) had the highest proportions of significant effects, compared to the other 3 study designs. Observational studies with control groups had significant effects generally somewhere between the RCTs and the before/ after observational studies (see Table 2). Process outcomes (eg, peak-flow-meter, use of an action plan, inhaler technique) improved more often after disease management than did clinical, medication, economic, and patient-reported outcomes, across all study designs. Clinical, medication, and economic outcomes that improved in response to disease management in the studies with the weaker study designs (after-only with control group, before/after without control group) were less likely to be significantly improved in the studies that had stronger study designs (RCT and before/after with control group).

These results highlight some of the challenges in interpreting the studies' results. The studies' quality was poor in several respects, including internal-validity threats from the study designs, lack of detail in the intervention descriptions, and issues in the analysis of outcomes (Table 3). Only 5 RCTs obtained treatment-effect estimates that were free of confounding. The other 22 studies were subject to bias from lack of randomization, which 2 studies

Table 3. Quality Factors in 27 Studies of Asthma Disease Management

Methodological, Presentation, and Estimation Issues	Number of Studies
Study-design issues	
Randomized patients	5
Control group included	15
Before and after assessment	24
Estimation issues for non-randomized studies	
No regression analysis	17
Limited covariate adjustment in regression analysis	3
Propensity score adjustment to quasi-randomize groups	2
Presentation issues	
Clear description of providers involved in intervention	25
Clear description of physician/nurse/pharmacist	4
interaction during study visits	
Clear description of physician-nurse/pharmacist	1
interaction between study visits	

addressed post-hoc by matching patients with propensity-score analysis.^{36,37} Seven of those 22 studies adjusted for regression to the mean by comparing pre-treatment and post-treatment outcomes, and for confounding by including a control group. The 3 after-only-with-a-control-group studies were subject to regression-to-the-mean effects, and the 12 before/after-without-a-control-group studies were not subject to regression to the mean but were subject to confounding issues. The extent to which the positive (and the negative or equivalent) findings of those 12 studies can be attributed to the intervention is unknown. Interpretation of those results was also complicated by the lack of regression analysis in 17 studies and limited covariate adjustment in regression analysis in 3 other studies.

Discussion

In this review we have described adult asthma diseasemanagement interventions, and evaluated whether the interventions affected health and economic outcomes. We also assessed the methodological quality of the studies, and we found that it was not possible to determine the interventions' impact on outcomes because of the differences in intervention components, study designs, and outcomes assessed. Five of the 27 studies were RCTs, and the remaining 22 studies used quasi-experimental designs, which are likely to have biased estimates of the interventions' effectiveness because they are subject to unobserved confounding and regression to the mean.³⁹ Our findings that the significance of the study results varied by study design and that studies based on RCTs had the lowest rate of significant results lend credence to that concern. Future studies should employ more rigorous study designs (eg, randomized trial or inclusion of a control group and before/after measurement) and should use multivariate statistical adjustment to reduce treatment-effect bias, such as propensity-score matching or instrumental variables. If those methods are not applied, then covariate and confounder adjustment should be as complete as possible.

Most of the studies had 2 notable omissions that would have provided greater context. First, few studies provided sufficient detail about physician/nurse/pharmacist interactions during and between office visits. Such detail is needed to identify the disease-management approach and to replicate all aspects of the intervention in different settings. Clear descriptions of those interactions would enable dissemination of effective approaches, because effective team communication may significantly improve patient outcomes.

Second, few studies provided the detailed costs and other statistics necessary to determine the cost-effectiveness or effect sizes of the interventions, so we were unable to examine cost-effectiveness and determine the value and return on investment, which would inform others interested in implementing the interventions. A recent cost/ utility analysis from a before/after study without a control group, of a disease-management intervention reviewed here,35 found that disease management was more effective and less costly than usual care.40 Future studies should clearly describe the costs included and excluded in the calculations (which one reviewed study did14) and explicitly examine cost-effectiveness with validated clinical and utility measurements. Without such information it is unclear whether the intervention merits dissemination. Future studies should also evaluate a broad range of patient and economic outcomes to comprehensively examine the impacts of disease management and identify which outcomes are most and least responsive to intervention in different disease-management models.

Summary

Disease-management programs have become a popular strategy to contain costs while improving health-care quality and patient outcomes. As disease management grows in popularity, effectiveness and cost-effectiveness assessments are important to ensure that these programs achieve their purpose. This review suggests that few well-designed studies with rigorous statistical evaluations have been conducted to evaluate disease-management interventions for adults with asthma. Current evidence is insufficient to recommend any particular disease-management model or intervention.

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